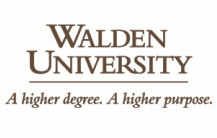

2017

Nutrition Services, Viral Suppression, CD4, and Retention in Ryan White Program Participants

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This is to certify that the doctoral dissertation by

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has been found to be complete and satisfactory in all respects,
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2017

Abstract

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by

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MPA, Syracuse University, 2007

BS, State University of New York, Buffalo State, 2001

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Public Health

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Abstract

The Ryan White HIV/AIDS Program (RWHAP) provides HIV-related medical and support services for uninsured and underinsured people living with HIV (PLWH) in the United States. In addition to HIV-related medical care, the program provides medical nutrition therapy and food assistance. The role of nutrition in the health of PLWH is well-documented, especially in resource poor areas; however, the role of medical nutrition therapy and food assistance provided through the RWHAP in resource rich areas is not well documented. This study addressed the association between the nutrition services of food assistance and medical nutrition therapy and the HIV-related health outcomes of viral suppression, retention in care, and CD4 counts. The behavioral model for vulnerable populations was used as the theoretical foundation for this quantitative cross-sectional study. A sample of 428 RWHAP clients was used from the Ryan White Services Report data. Pearson's chi-square was used to examine the association between medical nutrition therapy (MNT) and viral suppression. Findings indicated statistically significant associations between MNT and viral suppression, retention in care and any nutrition service (food assistance, MNT, or both), and MNT and retention in care. Implications for social change include emphasizing the role of nutrition services in HIV-related health outcomes for PLWH in resource rich areas.

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Dedication

To my husband, Jon. Your unwavering support is the reason I was able to keep going and to make it through! I love you!

Acknowledgments

To my family for their support throughout this process. It's been quite the ride and I'm glad that you hung on with me! Thank you for encouraging me to finish and being there to keep me sane along the way.

Thank you to my colleagues in the Division of Policy and Data in the Health Resources and Services Administration's HIV/AIDS Bureau. Without you, this research would not have happened. A special thank you to Antigone Dempsey, Tracy Matthews, Ruth Roman, and Stacy Cohen, for their support of the various parts of the research. Also, a big thank you to Vimal Rao and his team for running the data and being available to answer my questions.

I would also like to extend my sincerest appreciation to my committee: Dr. Donald Goodwin, my chair, and Dr. Gudeta Fufaa. Your guidance and support along this journey have been invaluable. Thank you for all of the time you invested in me and this research.

And finally, to my daughter, Phoebe. I hope this inspires you to reach for the stars and to not let anything stop you from making your dreams become reality.

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Chapter 1: Introduction to the Study

Background

In this study, I examined the potential association between nutrition services of medical nutrition therapy and food assistance available through the Ryan White HIV/AIDS Program (RWHAP) and HIV-related health outcomes of clients receiving those services, including viral suppression, retention in care, and CD4. Maintaining adequate nutrition is an important part of HIV care. Poor nutrition can cause the disease to progress at a more rapid rate and can lead to progression of the infection (Duggal, Chugh, & Duggal, 2012). There are many interventions that could be used to help HIV patients improve their nutritional status and reduce the impact of the illness on their health. Two nutritional interventions of interest in this study were dietary counseling and food assistance (Martinez et al., 2014; Palermo, Rawat, Weiser, & Kadiyala, 2013).

Dietary counseling, usually provided by a dietitian as medical nutrition therapy or by another qualified individual as nutrition counseling, is one way a patient could improve his or her nutritional status. Almeida, Segurado, Duran, and Jaime (2011) found that a 6-session nutrition intervention held over the course of 1 year had a statistically significant improved the consumption of fiber by over 10 grams. Lazzaretti, Kuhmmer, Sprinz, Polanczyk, and Ribeiro (2012) discovered that a 6-month dietary intervention achieved statistically significant changes in total blood cholesterol, triglycerides, and LDL cholesterol (bad cholesterol) between the intervention and control groups, as well as increases in HDL (good cholesterol) in both groups. The increases in HDL levels were due to viremic control associated with antiretroviral therapy. In addition, dietary

counseling can be used to address concerns regarding the role of medications on nutrition status (including drug-nutrient interactions), body composition changes associated with HIV, and other issues related to nutrition, malnutrition, and food that present with HIV infection (Fields-Gardner, 2010).

Food access also influences nutritional status. Lack of healthy, nutritious food (also known as food insecurity) can have a significant impact on a person's health. For HIV patients, Mendoza et al. (2013) concluded that food insecurity in pediatric patients was associated with lower CD4 counts and incomplete viral suppression. Food insecurity is also associated with obesity in HIV infected women (Sirotin, Hoover, Shi, Anastos, & Weiser, 2014). In addition, Frega, Duffy, Rawat, and Grede (2010) suggested there may be a multidirectional link between access to food and HIV infection; in patients who are less food secure, there is a greater chance of poorer outcomes. Weiser et al. (2009) determined that there was a statistically significant increase in nonaccidental mortality in a food insecure HIV infected population compared to HIV positive patients who were food secure.

At the same time, being HIV positive increases the likelihood that a family will be food insecure. Anema et al., (2011) found very high prevalence of food insecurity in the HIV positive population receiving antiretroviral treatment in a resource rich environment, with 71% of the study participants being ranked as food insecure. Food insecurity can also lead to negative uses of the health care system, such as increased usage of emergency rooms and recent hospitalizations (Weiser et al., 2013). Food assistance, such

as food bags or home delivered meals, may potentially help address food insecurity issues.

The RWHAP provides a safety net for low-income HIV infected patients who lack adequate health insurance. The program plays an important role in ensuring high quality HIV care to clients who might not have access to health care and support services (Sood et al., 2014). The grant-based program funds states and metropolitan areas with high incidence of HIV. Funds are used to provide a variety of health care services including primary HIV-related care, case management services, assistance in paying health insurance premiums, copayments and cost sharing, outpatient substance abuse treatment, and medical nutrition therapy (HIV/AIDS Bureau, 2016). The program also provides services such as transportation to and from medical appointments, housing assistance, and food assistance (food bank/prepared meals). In this study, I looked at the nutrition-related services provided by the program: medical nutrition therapy and food assistance.

Problem Statement and Purpose

Despite the documented importance of medical nutrition therapy and food assistance, there is a gap in the research as to whether patients who receive these services through the RWHAP have different levels of viral suppression, CD4 counts, or retention in care (being engaged in regular HIV-related health care; Mugavero, Davila, Nevin, & Giordano, 2010) when compared with RWHAP clients who do not receive these services. This study was conducted to fill that gap and to understand whether these services are associated with improved HIV-related patient outcomes. I used a quantitative cross-

sectional design to assess whether there is a relationship between food assistance and medical nutrition therapy and the health outcomes of viral suppression, CD4 count, and retention in care.

Research Questions and Hypotheses

Research Question1: Is there an association between receiving food assistance or medical nutrition therapy through the RWHAP and health outcomes such as viral suppression and CD4 counts?

Null Hypothesis ($H_0$1): There is no statistically significant association between receiving food assistance or medical nutrition therapy through the RWHAP and health outcomes such as viral suppression and CD4 counts.

Alternative Hypothesis (H_A1): There is a statistically significant association between receiving food assistance or medical nutrition therapy through the RWHAP and health outcomes such as viral suppression and CD4 counts.

Research Question 2: Is there an association between receiving food assistance or medical nutrition therapy through the RWHAP and retention in care?

Null Hypothesis ($H_0$2): There is no statistically significant association between receiving food assistance or medical nutrition therapy through the RWHAP and retention in care.

Alternative Hypothesis (H_A2): There is a statistically significant association between receiving food assistance or medical nutrition therapy through the RWHAP and retention in care.

Framework

Andersen's behavioral model of health services use was developed in the 1960s to predict and explain health care usage by families (Andersen, 1995). Over time the model was revised to focus more on individual usage. Additional revisions were made to accommodate the acknowledgement of the role environment plays in health care utilization and to include outcomes of health services.

The behavioral model for vulnerable populations is a modification of Andersen's behavioral model (Gelberg, Andersen, & Leake, 2000). It posits that the factors that make certain populations (such as the homeless) vulnerable may also affect their health care usage and health outcomes. According to this model, predisposing, enabling, and need components predict a person's health practice and health care usage, which lead to a person's health outcomes and health status. A visual representation of the model is provided in Figure 1.

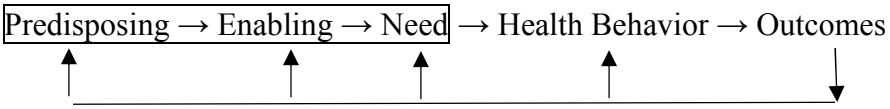

Figure 1. Behavioral model for vulnerable populations.

The predisposing component includes characteristics that are not easily changeable: age, gender, marital status, and social structure. For vulnerable populations, the predisposing component also includes characteristics such as immigration status, living conditions, criminal behavior, mental illness, and substance abuse. The enabling component includes characteristics that help support a person, such as personal resources, insurance status, income, and health services resources. For vulnerable populations, this

might include receiving public benefits, community crime rates, and the availability of social services within the person's community. The need component focuses on both perceived need and objective need for health conditions of the general population. For vulnerable populations, it includes the perceived and evaluated needs, such as sexually transmitted diseases and HIV. Personal health practices include activities such as diet, exercise, and adherence. They also include sources of food and food safety, as well as unsafe sexual behaviors. Outcomes include perceived and evaluated health status and satisfaction with care.

This model was ideal for this study because it provides support for the research questions and hypotheses. The RWHAP is providing nutrition assistance that impacts the population characteristics (primarily the enabling component) by providing community support (i.e., food assistance can be considered a social service) and information (medical nutrition therapy involves an information and educational component). The RWHAP also impacts personal health behaviors by providing skills to help patients improve their eating habits, as well as food to address health issues. The program also may help keep patients in care (retention) by ensuring that they go to their medical appointments so that they can get referrals or access to these other services. These two services then theoretically could lead to better health outcomes in the form of higher CD4 counts and viral suppression.

Nature of the Study

I conducted a quantitative study with a cross-sectional design because the data used for the analysis were gathered on an annual basis and a direct statistical relationship between the independent and dependent variables could not be established.

Key Variables

The independent variables in this study were receipt of medical nutrition therapy, food assistance, or both. The dependent variables were viral load, CD4 count, and retention in care.

Methodology

I analyzed secondary data collected by the Health Resources and Services Administration (HRSA). The data were from the Ryan White Service Report (RSR) (Health Resources and Services Administration, 2015a), which is reported to HRSA each spring by RWHAP grantees and is a combination of client, provider, and grantee level data. I examined the variables of receipt of nutrition services (medical nutrition therapy and food assistance), CD4 count, retention in care, and viral load.

Definitions

CD4 count: A laboratory test measuring the number of T lymphocytes (CD4 cells) in a person's blood, which are a type of white blood cell that plays an important role in fighting infection. In HIV infection, the virus destroys CD4 cells, lowering the body's defenses to infection. The CD4 count is important because it allows clinicians to monitor how well a patient's body is responding to antiretroviral treatment (ART) and provides an overall status of the patient's immune system. The CD4 count is used clinically in

determining how quickly ART needs to be initiated and when to start and discontinue prophylaxis for opportunistic infections and is a predictor in disease progression and survival (DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents, 2015). For this study, the Centers for Disease Control and Prevention's case definition for HIV was used to categorize program participants into levels by CD4 count. Stage 1 is a CD4 count of greater than or equal to 500 cells/μL or a CD4 percentage of total lymphocytes of greater than 26, Stage 2 is a CD4 count of 200 to 499 or CD4 percentage of total lymphocytes of 14 to 25, and State 3 is a CD4 count of less than 200 or CD4 percentage of total lymphocytes of less than 14 (Selik et al., 2014).

Food assistance: The generic name for support provided to clients to help ensure they have an adequate food supply. This can include a grocery bag of food (i.e., food pantry services), a hot meal (i.e., a soup kitchen), or a home delivered meal (i.e., a Meals on Wheels type program). The Ryan White Services Report lumps these services into one category for data collection (Health Resources and Services Administration, 2015a). This category also includes nutrition supplements not provided under the care of a registered dietitian and the provision of vouchers for food. Because these services cannot be broken apart, they were referred to as food assistance throughout this document.

Medical nutrition therapy (MNT): The treatment and prevention of disease by a registered dietitian or nutrition professional through assessment, setting nutrition-related goals and making a plan that includes counseling, therapy, education, and modification of diet (Fields-Gardner, 2010). In the RWHAP, MNT also includes the provision of

nutrition supplements and food pursuant to a medical professional's recommendation and a nutrition care plan (Health Resources and Services Administration, 2015a).

Outpatient/ambulatory medical service: Defined by the Health Resources and Services Administration (2015a, p. 7) as "the provision of professional diagnostic and therapeutic services directly to a client by a physician, physician assistant, clinical nurse specialist, nurse practitioner, or other health care professional certified in his or her jurisdiction to prescribe antiretroviral (ARV) therapy in an outpatient setting.

Retention in care: The definition used by the RWHAP was adopted, which is that the patient has two RWHAP outpatient/ambulatory medical service visits at least 90 days apart, with the first appointment occurring no later than September 1 of the reporting year, and a second visit at least 90 days after the first appointment (Health Resources and Services Administration, 2015b).

The *Ryan White Services Report (RSR)*: A client-level data set collected on an annual basis by the Health Resources and Services Administration to monitor impacts and outcomes in the RWHAP (Health Resources and Services Administration, 2015b).

Viral load: A laboratory test measuring Plasma HIV-1 RNA in a person's blood. It is useful for measuring sustained response to ART (DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents, 2015).

Viral suppression: Having a Plasma HIV-1 viral load of less than 200 copies on the most recent viral load test. A recent meta-analysis confirmed that in heterosexual serodiscordant couples (couples where one partner is HIV positive and the other is HIV

negative), viral suppression significantly decreases the rate of HIV transmission to the HIV negative partner in certain situations (Loutfy et al., 2013).

Assumptions

For this study, I assumed that the Ryan White Service Report (RSR) data had been accurately reported by the recipient grantees. The Health Resources and Services Administration provides significant technical assistance to grantees to ensure data are reported accurately. The agency also cleans, deduplicates, and organizes the data to ensure accuracy. I also assumed that there was a relationship between the medical services a client receives and the nutrition services provided at the same clinic or the clinic from which the client is referred for service.

Scope and Delimitations

I specifically addressed RWHAP clients who receive medical care through the program, in addition to receiving medical nutrition therapy or food assistance through the program. Given that the RSR data are specific to the RWHAP, the results of this study may not be generalizable beyond of the clients receiving services through the program; however, they could be applied to other grantees who chose to implement these services.

Limitations

One of the primary limitations of this study is the data. The RSR lumps food pantry services and home delivered meals into one category, along with nutritional supplements that are not provided under the care of a medical professional and food vouchers. This means that these individual items cannot be separated to determine whether one category is more significant than another. In addition, the use of secondary

data was also a limitation because it was originally collected for specific programmatic purposes and was not intended for outside research.

Significance

Study results may provide insight into one specific aspect of the RWHAP that has not been well studied: the association between specific health outcomes and nutrition related services in the RWHAP. Medical nutrition therapy and food assistance are very small components of the RHWAP, with only 0.79% of the program's Part A (grants to metropolitan areas and cities) service funds being allocated to medical nutrition therapy, and 3.73% of Part A service funds going to food assistance in 2013 (Health Resources and Services Administration, 2014a). For Part B (grants going to states), those amounts are 0.57% and 2.39%, respectively (Health Resources and Services Administration, 2014b). Despite the small amounts allocated to these services, there is the potential for larger impacts on people living with HIV (PLWH) who receive them.

In addition, as the health care landscape evolves because of the Affordable Care Act, understanding the potential association between these services and health outcomes is critical. The Affordable Care Act increases access to health insurance and health care for PLWH. As a result, other more traditional services provided by RWHAP, such as primary HIV-related health care and HIV-related medications, may have less demand as PLWH gain insurance coverage for these services. This study will enable the assessment of the RWHAP services not covered by insurance, including nutrition counseling and food assistance, to keeping people in care and having better health outcomes. Understanding the potential role for these services can lead to positive social change by

informing policy and programmatic decisions related to medical nutrition therapy and food assistance in the RWHAP. This can potentially increase the benefit of these services to the clients served by the program.

Summary

This chapter addressed the role of nutrition and nutrition interventions, such as medical nutrition therapy and food assistance, in HIV patients. I introduced the RWHAP and the nutrition services provided through the program and the role they may play in health-related outcome of CD4 counts, viral load, and retention in care. I also explained the behavioral model for vulnerable populations and its role as a framework for this study. Key operational definitions were introduced and an overview of the study's scope, assumptions, and limitations was provided. Chapter 2 presents a review of the literature regarding the role of nutrition interventions, the RWHAP, and the health outcomes of interest. Chapter 3 presents the research methods used for this study, and Chapter 4 presents the results of this study. Chapter 5 provides an interpretation of the study's findings and conclusions, as well as recommendations for further research and implications for positive social change.

Chapter 2: Literature Review

In this review, examine the current literature around HIV-related health outcomes, hunger and food assistance in the HIV infected population, and medical nutrition therapy including nutrition education and counseling. I also examine the literature around this study's framework, the Gelberg-Andersen behavioral model for vulnerable populations.

Literature Search Strategy

For this review, CINAHL and MEDLINE Simultaneous were the primary databases searched. Google Scholar was also used to find articles not available in full-text through Walden's library. When limited current research was identified on a topic, Thoreau (Walden University Library's multi-database search engine) was used.

The key search terms that were used were *HIV* and each of the following individually: *food assistance*, *food bank*, *food insecurity*, *food pantry*, *food security*, *food shelf*, *medical nutrition therapy*, *nutrition*, *nutrition education*, *nutrition counseling*, *nutrition assistance*, *retention in care*, and *viral suppression*. In addition, the *HIV care continuum*, *Ryan White*, and *RWHAP* were also used as search terms, as well as *CD4 count* by itself and with *outcome measure*. A search was also conducted for *viral hepatitis* and *HIV coinfection* (with no date limits). To ensure the most current literature was used, the search was limited to the years 2010 to 2015. Since the RWHAP's legislative mandate requires that the program only serve HIV positive individuals, the focus of this study was the impact of services for people living with HIV. As such, articles related to prevention of HIV or where subjects were not HIV positive were excluded (except as related to the study's framework). When limited research was

discovered relating to these topics, the reference list from relevant articles identified during the above-mentioned search was reviewed, leading to additional resources on key topics. This search strategy was primarily used for food assistance research, as the availability was limited. In addition, articles dealing with supplementation of macronutrients to address food insecurity were excluded, as this was not a focus of the study and not a service provided by the RWHAP.

To find research on the Gelberg-Andersen behavioral model for vulnerable populations, the key search terms were *behavioral model, behavioral model of health service, behavioral model for vulnerable populations, Gelberg-Andersen behavioral model for vulnerable populations, health service use, health service utilization, and health service use/model*. Because there was limited research using the Gelberg-Andersen behavioral model for vulnerable populations, the search was opened up to include all versions of Andersen's models, with no limit on the date the article was published.

Framework

I used the Gelberg-Andersen behavioral model for vulnerable populations as the study framework. This model is a revision of Andersen's behavioral model (Gelberg et al., 2000). Andersen's behavioral model was originally developed in the 1960s to predict and explain health care use (Andersen, 1995). Since then, several iterations of the model have been developed, including the one used for this study.

The behavioral model for vulnerable populations was first introduced in 2000 and was designed to understand the health seeking behaviors of at-risk populations such as the homeless (Gelberg et al., 2000). According to the model, issues that make a person

vulnerable, such as homelessness or certain disease states (such as HIV or mental health problems), may also impact his or her health status (including health outcomes and satisfaction with health services) and how he or she uses health services.

This model was chosen because it has been used extensively in the population of interest: HIV positive individuals. It has also been used in viral hepatitis-infected populations, which are similar to HIV positive populations in that they have similar risk factors and coinfection is common (Alter, 2006). Worldwide, approximately 10% of PLWH are coinfected with the hepatitis B virus and 25% are coinfected with the hepatitis C virus (Soriano, Vispo, Labarga, Medrano, & Barreiro, 2010). In addition, researchers have used versions of the behavioral model to predict which variables will impact health care utilization as well as health outcomes (Andersen et al., 2000; Anthony et al., 2007; Brennan-Ing, Seidel, London, Cahill, & Karpiak, 2014; Erlyana, Fisher, Reynolds, & Jansen, 2014; Gelberg et al., 2000; King et al., 2009; Mizuno et al., 2006; Stein, Andersen, & Gelberg, 2007; Stein, Andersen, Robertson, & Gelberg, 2012; Swanson, Andersen, & Gelberg, 2003).

The model has three components (also called domains): predisposing, enabling, and need (Gelberg et al., 2000). These three domains are theorized to predict personal health practices, which are theorized to impact health outcomes. Each of these three components are broken into traditional and vulnerable domains. The traditional domains are taken from earlier behavioral models aimed at the general population, while the vulnerable domains focus on social structures and resources that impact health care utilization, compliance, and health outcomes including patient satisfaction.

Predisposing factors are exogenous factors that play into the use of health care (Andersen, 1995). The predisposing traditional factors are primarily demographic characteristics and include things like gender, age, and social structure factors such as education, employment, and family size (Gelberg et al., 2000). The predisposing vulnerable factors are social structures such as living conditions, immigration status, and substance abuse. The predisposing domain items generally impact a person's social and community status and ability to deal with health problems, and to find resources to solve the health issue.

Enabling traditional factors are variables such as insurance status and income, as well as residence and physician-population ratio (Gelberg et al., 2000). The enabling vulnerable domain includes things like a family receiving food assistance and availability of information, as well community resources such as the availably of social services. Enabling factors include personal and community resources, both of which must be available if a patient is to utilize a health care service.

Finally, the need traditional domain includes perceived need and the evaluated need of general health conditions of the population (Gelberg et al., 2000). The need vulnerable domain focuses on perceived and evaluated need of those disease conditions that are of importance to vulnerable populations, such as HIV infection or tuberculous.

Andersen's models suggest that these three sets of characteristics then lead to health behaviors, which include personal health practices such as diet and exercise, as well as choices around food sources, safe/unsafe sexual practices, and which providers the person sees (Andersen, 1995; Gelberg et al., 2000). A person's health behaviors in

turn affect health outcomes, which include perceived and evaluated health status and satisfaction with care. Perceived status could be the person's perception of his or her heath, while the evaluated status would include items that concretely measure health status.

Andersen's various models have been used as a framework to support studies on health access and health outcomes in many vulnerable populations including PLHW (Andersen et al., 2000; Anthony et al., 2007; Brennan-Ing et al., 2014; Datti & Conyers, 2010; King et al., 2009; Mizuno et al., 2006), homeless (Gelberg et al., 2000; Stein et al., 2007, 2012; Swanson et al., 2003), those infected with hepatitis B and C (Stein et al., 2012), and others. Given the significant work with this model and health outcomes for PLWH, it was ideal as a framework for this study (Andersen et al., 2000; Brennan-Ing et al., 2014; Datti & Conyers, 2010; King et al., 2009; Mizuno et al., 2006).

Andersen's model has also been used to identify factors that predict seeing a health care provider in individuals recently diagnosed (Anthony et al., 2007). Factors that were associated with being seen by a provider include having more symptoms, being infected with viral hepatitis, having public health insurance, or case management. The behavioral model for vulnerable populations has been used to identify variables that impact viral suppression in HIV positive individuals (King et al., 2009). These variables include the predisposing variables of homelessness and drug use, both of which had a negative impact on the health outcome of viral suppression. Andersen's original model has been used to identify variables that would predict use of vocational rehabilitation services in HIV positive Latino men (Datti & Conyers, 2010).

This theory was chosen because it has demonstrated use with HIV populations. Researchers have used this model as a framework to explore health care utilization in various segments of this population, including the newly diagnosed PLWH; older PLWH; gay, lesbian, bisexual, and transgender PLWH; and injection drug users (Anthony et al., 2007; Brennan-Ing et al., 2014; Mizuno et al., 2006). The model has also been used to describe how the various factors (enabling, predisposing, and need) impact HIV treatment (Andersen et al., 2000). In addition, the model has been used to examine outcomes of health care in vulnerable populations similar to PLWH, including looking at retention in care for a population at risk for HIV (Haley et al., 2014), patient satisfaction in homeless women (Swanson et al., 2003), and general health outcomes in the homelessness population (Gelberg et al., 2000). I used enabling factors of hunger (assumed through the variable of use of RWHAP food banks) and information and social services (as identified by nutrition education and medical nutrition therapy) and the need factor of being HIV positive to examine the evaluated health outcomes of viral suppression, CD4 count, and retention in care.

Literature Review

Food security and good nutrition are important elements in HIV care. In the following sections, I review the current literature related to the impact of a lack of food security (food insecurity) and the role of nutrition in HIV-related health outcomes. I also discuss the literature on food assistance (the receipt of food or meals to improve nutrition or reduce food insecurity) and nutrition counseling (including medical nutrition therapy)

and the health outcomes of interest in this study (CD4 counts, retention in care, and viral suppression).

Overview of HIV

HIV's primary mode is to destroy the immune system. It does this by infecting and destroying specific white blood cells in the body, called T cells, which are the body's primary defense against infection (Moir, Chun, & Fauci, 2011). The virus enters these white blood cells via CD4 coreceptors. The virus then uses mechanisms in the white blood cell to replicate itself and spread throughout the body, slowly killing all of the infected person's T cells. Lower CD4 counts mean a higher likelihood of health issues and death related to HIV, as the infected person's immune system no longer functions to fight off infection.

ART works by interrupting this cycle and suppressing the virus (Chen, Hoy, & Lewin, 2007). There are several types of ART, each working through a different mechanism for interrupting the virus's reproduction cycle. For example, nucleoside reverse transcriptase inhibitors (NRTI) inhibit viral reverse transcriptase, which is an enzyme that is needed for the virus to replicate. Nonnucleoside reverse transcriptase inhibitors work by binding to the viral reverse transcriptase in a different spot than NRTIs. Protease inhibitors block HIV protease and prevent the virus from infecting other cells. Entry inhibitors or fusion inhibitors block HIV from entering the T cell at all. Other drugs work to block integrase, which is the enzyme used to integrate HIV RNA into the host cell.

Regular, consistent ART use can lead to viral suppression and a reduced risk of viral transmission. Retention in care is an important component of viral suppression (Yehia et al., 2014) because access to care leads to access to ART. Once PLWH are linked to and then retained in care, they may be able to achieve viral suppression and decrease the likelihood of poor health outcomes (Reveles et al., 2015).

Food Insecurity

Food insecurity is an important variable in HIV-related health outcomes. Researchers have identified strong links between food insecurity and poorer outcomes in PLWH, both in resource rich and resource poor areas (Palermo et al., 2013; Wang et al., 2011). In addition, food insecurity is associated with increased risk-taking behaviors such as having unprotected sex (Vogenthaler et al., 2013). In resource poor areas, food insecurity has been shown to be a barrier to taking ART (Weiser et al., 2010). Weiser et al. (2010) suggested that the medications are often taken with food, and if taken without food, some patients suggested that the side effects of the antiretroviral are exacerbated. Further, Weiser et al. noted that patients often worried about starting an ART regime because they were concerned they would not be able to complete it because of a lack of food.

For food insecure patients prescribed ART that is taken with food, there was statistically significant disparity between outcomes compared to patients who were prescribed ART that does not need to be taken with food (Kalichman et al., 2015). Of the 63% of study subjects who were food insecure, 57% had been prescribed ART to be

taken with food (Kalichman et al., 2015). These patients had lower CD4 counts, higher viral loads, and more HIV-related symptoms than the food secure study participants.

Food insecurity has also been linked to not being virally suppressed (Wang et al., 2011). Wang et al. (2011) found that in a population of HIV positive veterans on ART, 24% were food insecure. Of those, their viral load levels were higher, with a median viral load of 400 (*IQR* 75, 15,572) versus 359 (*IQR* 75, 3384) for their food secure counterparts ($p < 0.0001$) and were more likely to not be virally suppressed (adjusted *OR* 1.37; *CI* 95%, 1.09 – 1.73). Wang et al. discovered that food insecurity was also associated with low CD4 counts (*OR* 1.45; *CI* 95%, 1.14 – 1.86).

In a study of both HIV positive women and women at risk for HIV in the Bronx, there was a strong association with obesity (Sirotin et al., 2014). Sirotin et al. (2014) concluded that 31% of women in the study reported food insecurity with hunger, which is a more severe rating of food insecurity, as defined by the United States Department of Agriculture Food Security Survey Module. Food security has also been associated with increased acute care utilization in HIV positive homeless and marginally housed patients (Weiser et al., 2013). Weiser et al. (2013) found that food insecurity was statistically significantly associated with the likelihood of having been hospitalized or to have visited an emergency room in the most recent 3 months.

A study of PLWH living in Atlanta, Georgia, concluded that those that reported food insecurity over the last twelve months also had reported more HIV symptoms, as identified in a scale of 14 related symptoms (Kalichman et al., 2010). While this study observed it less likely that these individuals were virally suppressed (*OR* 1.7; *CI* 95%, 1.1

– 3.0) and were more likely to have a lower CD4 count (t=2.2, p<0.05), according to Kalichman et al. (2015) the type of ART a food insecure patient was prescribed (ART needing to be taken with food versus ART taken without food) impacts adherence, which would impact viral suppression and CD4 counts. Those patients prescribed ART that had to be taken with food fared worse than those that were prescribed ART that did not require food. In addition, according to Kalichman et al., (2010), those patients reporting food insecurity were much more likely to report barriers to staying in HIV treatment, such as not being able to being able to afford medications (*OR* 4.2; 95% *CI*, 1.3 – 13.1) or not having transportation to get to the clinic (*OR* 4.9; 95% *CI,* 3.1 – 8.0). Further those who were food insecure on ART over time had smaller increases in CD4 counts than their food secure counterparts (McMahon, Wanke, Elliott, Skinner, & Tang, 2011). However, given the findings of Kalichman et al., (2015), whether food insecure patients are prescribed ART that must be taken with food should be considered when looking at changes in CD4 counts or other HIV-related health outcome measures.

One meeting abstract examined food security and RWHAP. The study found that 77% of the RWHAP food and nutrition service clients in the New York City jurisdiction were food insecure and this was associated with an unsuppressed viral load (Alexy, Feldman, Thomas, & Irvine, 2013).

Nutrition in HIV

Nutrition plays a key role in HIV care. Deficiencies of certain micronutrients, malabsorption, wasting disease, and weight loss each impact health outcomes in HIV infection and are important nutrition considerations in care of a PLWH (de Pee & Semba,

2010). In addition, there are significant drug-nutrient interactions that impact bioavailability of ART in HIV treatment that must receive consideration (Raiten, 2011). Further, a Kenyan study determined there was an association between higher CD4 counts in male patients and adequate protein intake, which may indicate a role for medical nutrition therapy to educate on diet and macronutrient consumption to support improvements in HIV-related outcomes (Vaughan, Cardenas, & Keiser, 2013). Further exploration of this topic is warranted to provide information on the role of diet, especially protein, on HIV-related outcomes.

Nutrition Education and Medical Nutrition Therapy

Nutrition interventions such as nutrition education and medical nutrition therapy are one way to address nutrition issues in PLWH, as well as to help alleviate food insecurity (Claros, de Pee, & Bloem, 2014; Martinez et al., 2014). These services can also be used to address health outcomes in this population, as many of the medications used to treat HIV and related health concerns either require specific dietary interventions (i.e., require that medications be taken with food or certain amount of fat) or there are dietary implications due to these medications, such as dyslipidemia. In particular, for people who are food insecure, Kalichman et al., (2015) found that these patients were more often prescribed ART that was required to be taken with food and had worse adherence, lower CD4 counts, and were less likely to be virally suppressed than their food secure counterparts.

There are many benefits to nutrition education and medical nutrition therapy for PLWH. For example, HIV positive patients in South Africa receiving nutrition education

are less likely to be food insecure (p=0.014), as well as less likely to have reported being sick in the last thirty days (p=0.037) or, if they were sick, to have milder symptoms (p=0.038) (Oketch, Paterson, Maunder, & Rollins, 2011). Nutrition education can also help improve eating habits, such as increasing consumption of healthy fats and fiber, even if associated health outcomes are not seen in the short term (Almeida et al., 2011).

Nutrition education can also improve treatment adherence. In a study in Honduras that provided nutrition education, it was found that treatment adherence, which included fewer missed appointments, less delay in prescription refills, and few self-reported missed ART doses, improved (Martinez et al., 2014). This study, however, did not have control group to compare just nutrition education, as it was also looking at food assistance and the potential additive effect of food assistance on nutrition education and HIV related health outcomes.

Further, nutrition education can reduce dyslipidemia associated with HIV infection and ART usage. A study by Lazzaretti, Kuhmmer, Sprinz, Polanczyk, and Ribeiro, (2012) found that patients receiving targeted nutrition education had significantly less hypercholesterolemia and Hypertriglyceridemia (p=0.001 for both). This study also concluded that significantly fewer patients developed lipid profiles capable with the diagnosis of dyslipidemia.

Food Assistance

Food assistance is another potential way to address food insecurity, not only in PLWH, but also in the general food insecure population. It may also help with retention in HIV care by decreasing the hunger and helping patients to meet their food needs

(Aberman, Rawat, Drimie, Claros, & Kadiyala, 2014). Depending on the setting, it could include receiving a bag of groceries to prepare at home (often called a food pantry, food shelf, or food bank), a hot meal eaten onsite (e.g., a soup kitchen), or a prepared meal delivered to the patient's house (e.g., a Meals on Wheels type program). In the RWHAP, there is not a clear sense as to what format food assistance takes, but anecdotally, food pantry services are the most likely form for it to take. In the RWHAP, food assistance, like the other support services provided by the program, is intended to support the patient in care (Sood et al., 2014).

In resource poor areas, food assistance has been shown to improve health. For example, a program in Uganda that provided food assistance to poor, food insecure ART naïve patients (those new to ART) has statistically significant increases in health-related quality of life (HRQoL) indicators (Maluccio, Palermo, Kadiyala, & Rawat, 2015). This study found that there was a statistically significant increase of 6.75 ($p \leq 0.01$) in HRQoL subscale score for general health perceptions in people receiving assistance (Maluccio, Palermo, et al, 2015, Table 3), as well as a statistically significant decrease in the number of self-reported symptoms ($p \leq 0.01$).

In a study in rural Rwanda, community accompaniments, which included a monthly food package for family of four, have been shown to increase retention in care and viral suppression than those patients who did not receive the community accompaniments (Franke et al., 2013). In this study those patients receiving the added food and support benefit had a 15% greater chance of being retained in care and virally

suppressed after one year, as compared to the patients only receiving clinical care (*RR*: 1.15; 95% *CI*:1.03–1.27; $p = .01$).

One program in Uganda provided food packages to eligible families, based on family composition, income/assets, and commitment to participate in the sponsoring organization's program (Rawat, Faust, Maluccio, & Kadiyala, 2014). While this study did not find significant impact on nutritional outcomes of BMI and hemoglobin counts, it did find that mean Household Food Insecurity Access Scales cores dropped by 2.1 points in participants.

A study in a poor area of Haiti where patients received World Food Programme food rations found that HIV patients receiving this food assistance had better food security than those that did not receive the assistance. This difference was noted at both 6 and 12 months per Ivers, Chang, Jerome, and Freedberg (2010); mean food insecurity score of -3.55 versus -0.16 in the non-food assistance group, $p<0.0001$). This study also found significant improvements in BMI for the food group as compared to the group not receiving food assistance. At 6 months, the BMI had fallen in both groups, but less in the food group, while at 12 months, the food assistance group had increased its BMI, while the group not receiving assistance did not. Also, adherence to monthly clinic visits was better with the food assistance group, with 9.73 visits versus 8.34 for a 12-month period ($p=0.0007$).

There are other benefits of food assistance provided to PLWH. Food assistance also was found in Uganda to impact weight gain and to slow HIV disease progression (Rawat, Kadiyala, & McNamara, 2010). It has also been shown to help with ART

adherence in resource limited settings, such as Mozambique and Zambia; however, the results are mixed on the issue (Posse, Tirivayi, Saha, & Baltussen, 2013; Tirivayi, Koethe, & Groot, 2012). Posse et al. (2013) found that there were no significant differences in adherence between patients who received food assistance for 6 or 12 months and those who did not. In fact, the nonsignificant difference in average impact between the food assistance group and the control was only 0.4% (p=0.94) at 6 months and -2.3% (p=0.73) at 12 months. On the other hand, Tirivayi et al. (2012) discovered adherence was higher after 6 months of food assistance compared to non-recipients (98.3% versus 88.8%; p<0.01). According to de Pee, Grede, Mehra, and Bloem (2014), one of the reasons for this difference is the study by Posse et all, provided food unconditionally at a different location than the clinic, so patients could continue to get food without attending their clinic appointments. This may not have been the case in Tirivayi et al (2012).

Palar et al., (2015) found that in in HIV-infected patients in Honduras who were receiving a nutrition education intervention, who were also on ART, food insecurity decreased in those receiving both nutrition education and food assistance. This study also concluded that there was an increase in body weight for the overweight participants (p<0.01), which could lead to negative health consequences. With this particular study, the inclusion of nutrition education for both groups, without a control group, limited the utility of the study related to the impact of food assistance on health outcomes, such as body weight.

While there is clear benefit to using food assistance in resource poor settings to address food insecurity, the role of food assistance has not been well studied in resource rich environments (like the United States). No studies were identified looking at food assistance specifically in PLWH in resource rich settings or any looking at food assistance in the RWHAP. However, there was one meeting abstract retrieved that examined food insecurity and viral suppression in a population of PLWH who were receiving food and nutrition services through the RWHAP (Alexy, Feldman, Thomas, & Irvine, 2013). Further, there were no studies located that looked at food quality or nutrition density of the food provided through food assistance packages to PLWH. Nutrient density is a debated topic, but generally describes whole food and drink that have vitamins, minerals, or other properties and are limited in solid fat and added sugar that can lead to adequate nutritional intake (U.S. Department of Health and Human Services and U.S. Department of Agriculture, 2015). Food quality and nutrition density are both issues that might impact health related outcomes and retention in care and could have significant impact of the result of all of the studies that were reviewed for this particular section of the literature review.

Health Outcomes

Two of the three health outcomes are based on the HIV care continuum, which is framework for assessing engagement in care and HIV-related care outcomes (Gardner, McLees, Steiner, del Rio, & Burman, 2011). The stages of the HIV care continuum are diagnosed with HIV; linked to care; retained in care; prescribed ART; and virally suppressed (Office of National AIDS Policy, 2013).

Retention in care and viral suppression are two measures that indicate a progression along the HIV care continuum. According to recent data, of the estimated 1.2 million people infected with HIV in the United States, just over 437,000 are retained in care, and almost 210,000 are virally suppressed nationwide (Gardner et al., 2011). In the RWHAP, which serves just over 500,000 people each year, the rate of PLWH served by the program who were retained in care is at 82.2% and viral suppression is at 72.8%, which are higher than the national rates for retention in care (37% – 40%) and viral suppression (19% – 28%) (Doshi et al., 2015). The study proposed in this document will look at these two variables to determine whether there is an association between receiving RWHAP services of food assistance or medical nutrition therapy and being retained in care and being virally suppressed.

Retention in care and viral suppression are highly linked. One study found that having more missed appointments (as a proxy for not retained in care) led to a 20% increased change in not being virally suppressed for each additional missed appointment during the last 12 months (Zinski et al., 2015). Further, the interaction between retention in care and viral suppression (e.g., retained and suppressed, retained and not suppressed, non-retained and not suppressed) had variability over time with just over half of the participants in one study maintaining the same status over a 2-year period (Yehia et al., 2015).

In addition, in resource poor areas, such as a study in rural Rwanda, providing a community-based treatment model can have a positive impact on retention in care and viral suppression (Rich et al., 2012). This model was integrated into primary care and

included supports, such as medical transportation and nutrition assistance to help PLWH stay in care and on treatment. This is a similar model that is used in the RWHAP, which uses a system of care to provide those services that help people get into care, on ART, and then virally suppressed.

CD4 counts are not as commonly used for outcomes measures programmatically, but they do still serve an important clinical role. They are generally used to determine stage of HIV infection (Stage 1 is a CD4 count of greater than or equal to 500 cells/μL or a CD4 percentage of total lymphocytes of greater than 26, Stage 2 is a CD4 count of 200 - 499 or CD4 percentage of total lymphocytes of 14 – 25, and State 3 is a CD4 count of less than 200 or CD4 percentage of total lymphocytes of less than 14; (Selik et al., 2014)). They are also used to monitor ongoing disease progression and severity.

Further, patients with higher initial CD4 counts were at a greater likelihood of viral suppression and rates of viral suppression were higher with patients retained in care (Yehia et al., 2014). This study also indicated that for PLWH with lower initial CD4 counts, there was greater disparities for viral suppression between PLWH who were retained in care and those who were not, as compared to people with higher initial CD4 counts. This suggests a link between CD4, retention in care, and viral suppression. CD4 is also a strong predictor of death, but is modified by viral suppression and time on ART (Brennan, Maskew, Sanne, & Fox, 2013).

Summary

This chapter outlines the literature review strategy for locating and finding current research on the topic. It then provides a summary of the current research around the

framework for this study, the Gelberg-Andersen behavioral model for vulnerable populations. It outlines the framework's use with PLWH and other similarly vulnerable populations.

I then discuss research around two important issues in HIV: food insecurity and nutrition. Food insecurity is an important issue to address in PLWH, as it leads to barriers for HIV-related treatment and as well as to taking ART. Food insecure PLWH often have worse HIV-related health outcomes, such as not being retained in care, and are less likely to be virally suppressed. They may also have lower CD4 counts and need to access emergency room and acute care health services more often than food secure individuals may. Related, good nutrition is an important component of HIV-care, as nutrition deficiencies may have an impact on health outcomes of PLWH.

It also provides additional background on the two broad activities aimed at addressing poor nutrition and food insecurity to improve viral suppression, retention in care, and CD4 counts: nutrition education and food assistance. Nutrition education has been shown to increase treatment adherence and to reduce food insecurity, which are likely to impact the HIV-related health outcomes of interest for this study. In resource poor areas, food assistance has been shown to increase health-related outcomes, increase food security, and slow HIV progression, but limited research is available on effectiveness in resource rich areas.

Finally, it concludes with a discussion of the health outcomes of interest in this study: retention in care, viral suppression, and CD4 counts. HIV is a very complex disease and HIV-related health outcomes are impacted by many factors, including social

factors, demographics, health status of the infected person, and access to care and treatment. The three outcomes of interest in this study, CD4 counts, viral load, and retention in care, are all impacted by these factors.

Retention in care and viral suppression are two important points that measure progress along the HIV care continuum, whereas CD4 counts are emphasized less these days, but provide a basis measure of the immune function of a PLWH. Retention in care provides a measure for how well PLWH stay in care and have access to life-saving ARTs, which can lead to viral suppression and often an increase in CD4 count.

This study looked at the role that food assistance and nutrition education/medical nutrition therapy had in helping PLWH stay in care and on their medication, thus impacting viral suppression and possibility even CD4 counts. The research suggested that food assistance and nutrition education may have an impact on these HIV-related outcomes; however, the role these services play in the context of the RWHAP has not been clearly studied.

Chapter 3: Research Method

I examined HIV-related health outcomes of viral suppression, CD4 counts, and retention in care of PLWH who receive nutrition-related services in RWHAP. The primary analysis was conducted using the RSR, which is a data set of all PLWH who receive services through the RWHAP, as reported by program recipients (e.g., states, cities, universities, and HIV clinics).

Research Design and Rationale

For this study, I used a quantitative cross-sectional design. This type of design was chosen in part because of its common use in social sciences and the fact that the data are representative of a single point in time (Frankfort-Nachmias & Nachmias, 2008; Mann, 2003). As described in Chapter 1, the data are collected once each year; however, the viral load and CD4 counts may have been taken at any point during the year and may or may not directly coincide with the date of receipt of medical nutrition therapy or food assistance. Although a cross-sectional design cannot be used to determine a causal relationship, it can be used to identify an association between the variables. The RSR data set is the only national data set that has health outcomes for PLWH and includes PLWH who have received the nutrition assistance services of interest in this study. A cross-sectional design was appropriate due to the limitations imposed by the use of existing data. It would not have been practical to collect additional data at the national level to look at this issue across the entire RWHAP. There is limited literature on the impact of nutrition services on HIV-related health outcomes, especially CD4 counts, viral

suppression, and retention in care. Given this gap in the literature, this was an appropriate starting place for this research.

Methodology

Population

The target population was PLWH ages 13 and older who receive medical nutrition therapy or food bank services and outpatient/ambulatory medical service through the RWHAP. Under RSR reporting requirements, only clients who receive an outpatient/ambulatory medical service are required to have a viral load or CD4 count reported to the RSR. Further, retention in care is defined as RWHAP outpatient/ambulatory medical service visits at least 90 days apart, which is why only patients who had received outpatient/ambulatory medical service were included in this study, as the required dependent variables were not available for those not receiving this service. The data set included 492,240 PLWH, although not all of those receive an outpatient/ambulatory medical service visit (Health Resources and Services Administration, 2015b).

Sampling and Sampling Strategy

Choosing an appropriate sampling design is important because it allows statistical results to be more generalizable to the larger populations of interest in a particular study (Frankfort-Nachmias & Nachmias, 2008). The total data set was divided into four groups: RWHAP clients who received food assistance, RWHAP clients who received medical nutrition therapy, RWHAP clients who received both food assistance and medical nutrition therapy, and RWHAP clients who received neither service. Given the

potentially large size of the data set for this study, a systematic sample was applied to each group to identify a sample for analysis from each group to ensure similar size for each of the groups for analysis. A systematic sample means that every K^{th} entry will be selected (K = total population/sample size needed). It is often used with large populations or when a larger sample is needed (Frankfort-Nachmias & Nachmias, 2008). No additional stratification of demographic or variables occurred. In this type of sample, each sampling unit in the data set has a 1/K probability of being selected. Although this strategy is a straightforward way to identify a sample, it may allow the introduction of bias if there is a pattern to the data that occurs at every K^{th} unit. Although this phenomenon was assumed to not have been likely in this particular data set given the size of the population and that the dataset was not arranged in a particular order, it must be mentioned as a possible source of bias.

Sample Size and Power Analysis

Sample size is also important in a study design because it impacts the researcher's ability to correctly accept or reject the null hypothesis (Cohen, 1992). Cohen's (1992) paper on statistical power was used as a guide to determine the minimum sample size. I determined that for the chi-square statistical test with a power of .80, α of .05, medium effect size, and 2 degrees of freedom, the appropriate sample size was 107 for each group, equaling a total of 428 to ensure statistical power.

Variables

The independent variables were receipt of medical nutrition therapy and food assistance. Both of these variables were dichotomous (yes/no). The dependent variables

were viral suppression, CD4 count, and retention in care. Viral suppression was dichotomous and was defined as having a Plasma HIV-1 viral load of less than 200 copies on the most recent viral load test. Those clients with the most recent viral load of less than 200 copies/mL were coded as 1 for viral suppression and 0 if the latest viral load was greater than or equal to 200 copies/mL and the client was not virally suppressed.

The variable of CD4 count was an interval variable, but was coded as categorical using the CDC surveillance case definition: Stage 1 is a CD4 count of 500 cells/mL or greater, Stage 2 is a CD4 count of 200-499 cells/mL, and Stage 3 is a CD4 count of less than 200 cells/mL. Although this transition from an interval variable to a categorical variable may have resulted in some loss of information and a reduction in the power of analysis, it allowed for a simpler categorization of health outcomes for this particular variable and aligned with current practice for CDC surveillance data (Selik et al., 2014).

Retention in care was also a dichotomous variable. Patients were considered retained in care if they had at least two outpatient/ambulatory medical service visits at least 90 days apart during the course of a year, with the first occurring by September 1 of the reporting year and the second at least 90 days after. Retention in care was coded as 1 for retained and 0 for not retained. If the patient had only one outpatient/ambulatory medical service in a year, he or she was coded as not retained unless the visit occurred after September 1, and then it appeared as if the variable was missing for that case. If the client received two or more visits at least 90 days apart, the client was coded as retained.

Data Analysis Plan

The following research questions were addressed in this study:

Research Question 1: Is there an association between receiving food assistance or medical nutrition therapy counseling through the RWHAP and health outcomes such as viral suppression and CD4 counts?

Null Hypothesis ($H_0$1): There is no statistically significant association between receiving food assistance or medical nutrition therapy through the RWHAP and health outcomes such as viral suppression and CD4 counts.

Alternative Hypothesis (H_A1): There is a statistically significant association between receiving food assistance or medical nutrition therapy through the RWHAP and health outcomes such as viral suppression and CD4 counts.

Research Question 2: Is there an association between receiving food assistance or medical nutrition therapy through the RWHAP and retention in care?

Null Hypothesis ($H_0$2): There is no statistically significant association between receiving food assistance or medical nutrition therapy through the RWHAP and retention in care.

Alternative Hypothesis (H_A2): There is a statistically significant association between receiving food assistance or medical nutrition therapy through the RWHAP and retention in care.

IBM SPSS Statistics (SPSS), version 21, was used to conduct the statistical analysis. Data were checked for inconsistencies such as outliers and missing data. The chi-square statistical test was used to answer the research questions. Chi-square tests were chosen for this analysis because the outcomes for the research questions were all categorical variables.

Archival Data Procedures

The RSR contains annual client level data reported by funded recipients on the clients they serve. It is used to monitor outcomes of PLWH and families who get medical care and support services through the RWHAP (Health Resources and Services Administration, 2015b). It is also used to monitor progress toward achieving the goals of the National HIV/AIDS Strategy, Updated to 2020, as well as to provide feedback to the Department of Health and Human Services, Congress, and other key stakeholders on the progress the RWHAP has made to impact the epidemic.

All recipients who use RWHAP to provide core medical (as defined by the RWHAP) or support services to clients must report certain information on the clients they serve, depending on which service is provided. Data are entered into the RSR system by recipients in early spring of each year. An encrypted unique client identifier is used to ensure data are limited only to what are needed by the program.

To gain access to the RSR data set, a formal data request was made to the Health Resources and Services Administration, HIV/AIDS Bureau, Division of Policy and Data via an internal process (V. Rao, personal communication, April 7, 2016). An analyst worked directly with the requestor to clarify the request and ensure that the correct data had been pulled. In addition, the request included the specific variables needed, the reason for the data request, and who will have access to the data. Once the request was approved, a data use agreement (DUA) was required (see Appendix A). Once an approved DUA was on file, access was granted for the requested data and was allowed for the duration of the project. Data were handled per the instructions in the DUA.

Threats to Validity

One of the major threats to the validity of this study was the concern that the dependent variables and the independent variables could not be directly linked. The RSR is reported on an annual basis; however, receipt of medical nutrition therapy and food assistance are only reported as a yes/no variable received during the year, while dates are reported for all outpatient/ambulatory medical services, viral load testing, and CD4 results (Health Resources and Services Administration, 2015a). Because the dates of services are unknown, this made it impossible to directly link receipt of these services to HIV-related health outcomes, which is a major weakness of this study.

In addition, the data are entered into the RSR system directly by recipients of funding or via import from an electronic medical record. Data are collected from approximately 2,000 recipients and subrecipients (Health Resources and Services Administration, 2015b). Despite technical assistance and training, there may be missing data or incorrectly reported data that might impact the quality of what is reported and analyzed.

Ethical Procedures

To access RSR data, the Health Services and Resources Administration gave permission to use the data (A. Dempsey, personal communication, November 3, 2015). Once permission was granted, a data use agreement was signed and approved. Once the DUA was signed, the agency granted access to the requested data. Each record was identified by an encrypted unique client identifier. Data were handled, stored, and destroyed as described in the DUA.

One ethical issue of note is that I am employed by the Health Services and Resources Administration, HIV/AIDS Bureau, which is the organization that administers the RWHAP nationally. In this role, I have access to privileged, predecisional information. I ensured that my role as a student researcher and an employee were separated so that my professional position did not bias the study or interpretation of the results. I abided by all IRB approved protocol and the legally binding DUA. Walden University IRB approval #08-12-16-0197756 was obtained on August 12, 2016 to conduct the study.

Summary

This chapter provided a detailed overview of the research design and methods that were used. It also presented an overview of the methodology and description of the data set that was analyzed. It also addressed some of the potential threats to validity and ethical issues that were considered as part of this study.

Chapter 4: Results

The purpose of this study was to examine the association between the nutrition services of food assistance and medical nutrition therapy provided by the RWHAP, and the HIV-related health outcomes of viral suppression, CD4 count, and retention in care using the 2014 RSR. Research has indicated that nutrition services may have a positive impact on HIV-related health outcomes including helping to keep PLWH retained in care. This chapter presents the results of the 2014 RSR cross-sectional data analysis and findings of the hypotheses in this study. The research questions addressed by this study were the following:

1. Is there an association between receiving food assistance or medical nutrition therapy in the RWHAP and health outcomes such as viral suppression and CD4 counts?
2. Is there an association between receiving food assistance or medical nutrition therapy in the RWHAP and retention in care?

Data analysis included descriptive statistics on demographic characteristics of the sample and clinical variables in the study. In addition, this chapter provides results of statistical analyses to answer each of the research questions.

Data Collection

IRB approval was obtained on August 12, 2016. Once approval was obtained, a data request was submitted to the Health Resources and Services Administration. The data were received within a week, along with a variable codebook. The data file was uploaded into SPSS 21.0 for analysis. The only discrepancies from the original data plan

was that the entire data set was provided, instead of RWHAP participants ages 13 or older, and who had received an outpatient ambulatory medical visit during the data reporting period. Because the entire data set was provided, cases for people under the age of 13 and those who had not received an outpatient ambulatory medical visit during the year were filtered out. Clients receiving an outpatient ambulatory medical visit are the only ones for whom a viral load test or CD4 count are required to be reported to the RSR, and the only clients for whom retention in care can be calculated. Those clients who had not received an outpatient ambulatory medical visit were originally removed from the population by filtering out any case that was missing a retention in care variable; however, after the analysis was conducted, I determined that this method also removed clients who had an outpatient ambulatory visit after September 1 of the reporting year, as those cases would be coded as missing instead of not retained in care. After consultation with HRSA, I determined that an additional variable was needed that would allow the data set to be filtered for outpatient ambulatory medical care. This new variable of outpatient ambulatory medical care was coded as 1 for receiving outpatient ambulatory medical and 0 for not receiving outpatient ambulatory medical care. From this revised data set, I filtered the data to get only those age 13 and up who received an outpatient ambulatory care visit during the reporting period, selected a new sample, and reran the data analysis.

In addition, nutrition assistance was coded as one variable in the data set received: 1 for food assistance, 2 for MNT, 3 for food assistance and MNT, and 4 for no nutrition assistance. For this analysis, the variable was recoded into five separate variables, each

dichotomous with a 1 for receiving the service, and 0 for not receiving the service. The five variables were food assistance (receiving food assistance =1), MNT, food assistance and MNT, no food assistance (not any food assistance =1), and a fifth variable that combine all forms of nutrition assistance (1 for receiving food assistance, MNT, or MNT and food assistance).

Results

Descriptive Statistics

In 2014, 512,214 clients were reported to the RSR. This included both PLWH, as well as a small population (19,974) of uninfected individuals who were affected by HIV and received services as a result (e.g., family center counseling or respite care services) (Health Resources and Services Administration, 2015). Examples of affected individuals included people caring for a PLWH or family member of someone living with HIV. For this analysis, only the 304,366 PLWH who had received an outpatient ambulatory medical visit during the reporting year were studied. Information was reported on five demographic variables: age, race/ethnicity, gender, health insurance status, and poverty level. Age was reported as actual age in years. Gender was categorical and reported as male, female, or transgender. Race/ethnicity was reported as a categorical variable and possible responses included White, Black, Asian, Native Hawaiian/Pacific Islander, American Indian/Alaskan Native, Multiracial, or Hispanic. Health insurance status was reported as having no insurance, Medicare only, insurance from a private employer, private insurance purchased by the client (e.g., plans purchased through the Marketplace set up by the Affordable Care Act), Medicaid only, Veterans Administration benefits or

Tricare, health benefits through the Indian Health Service, other, both Medicaid and Medicare, or multiple insurances throughout the year. Poverty level was reported as greater than 500, 401–500, 251–400, 139–250, 100–138, or less than 100% of the federal poverty level. Client income was not provided; this variable was calculated as part of the data request. Age, race/ethnicity, and gender are required for all services provided, while health insurance is only required to be reported for clients receiving legislatively defined core medical services (outpatient ambulatory medical care, medical case management, medical nutrition therapy, etc.). Poverty level is only required if a client receives outpatient ambulatory medical care. In addition, viral suppression was calculated from the last reported viral load test of the reported year as part of the data request. Retention in care was also calculated as part of the data request and was provided to me as a separate variable. Whether a patient was retained in care was calculated only for PLWH receiving at least one outpatient ambulatory medical care visit in the reporting year. For CD4 count, the last laboratory test of the year was provided as part of the data request. I then recoded the variable based on the CDC case definition for HIV. Viral load and CD4 count were only required for clients receiving an outpatient ambulatory medical care visit. Because the date was not available for either CD4 or viral load, it is not known whether these two laboratory tests were taken at the same time or at different points during the year. The coding and possible responses for each of these variables, as well all other variables received as part of the data request, are outlined in Appendix B.

The sample was drawn using a systematic random sample. No additional stratification by demographic variables occurred or was taken into account in determining

the sample size. I used the Complex Samples module in SPSS to draw the sample. The nutrition assistance category was divided into four groups: RWHAP clients receiving food assistance, MNT, food assistance and MNT, and no nutrition assistance. An equal systematic random sample was pulled from each group. The seed values (the first case selected) were determined randomly by SPSS, and 107 cases were pulled from each nutrition assistance value (food assistance, MNT, food assistance and MNT, and no nutrition assistance) for a total of 428 cases.

Of the 428 clients in the aggregate sample, which was made up of the four proportional groups (RWHAP clients receiving food assistance, MNT, food assistance and MNT, and no nutrition assistance) sampled from the full population, the average age for clients receiving services was 46.3 (*SD* = 11.9, Range 1–65 years). Most of the clients served were male (71.3%) and .2% were transgender. About half of the clients were Black (51.2%), slightly less than a quarter were White (21.9%), and 22.2% were Hispanic. The majority were poor, with just over 70% falling below 100% of the federal poverty level. Many of the clients were either uninsured (25.4%) or had Medicaid (34.4%). A smaller percentage received Medicare alone (10.5%) or in conjunction with Medicaid (12.4%). The average viral load test was 14,330.9, with tests ranging from 0 to 999,420 copies, a median result of 20.5, and three quarters of viral loads falling below the threshold for viral suppression. For CD4 counts, 49.8% fell in to the CDC's case definition for Stage 1, 37.3% fell into the Stage 2 definition, and 12.9% fell into Stage 3. Over 81% were retained in care, and almost 80% were virally suppressed.

In the full population of 304,366 of clients who received an outpatient ambulatory medical visit that year, the mean age for a client was 44, with a range from 13 to 97 and a standard deviation of 12.3. Of the 304,366 receiving outpatient/ambulatory heath care, 70.8% were men, 28.1% were women, and 1% were transgender. Just under half the clients were Black (46.6%), 25.1% where White, and 24.6% were Hispanic. Many of the clients were poor, with 63.6% earning less than 100% of the federal poverty level; 30.4% of the population were uninsured; and 31.1% had Medicaid. Medicare was used as the primary health care coverage for about 8.8%, and 6.4% were dually covered by Medicare and Medicaid. The average viral load test was 15,104.4, with tests ranging from 0 to 113,071,968 copies, with 81.4% falling within the range of being virally suppressed (having a viral load test less than 200 copies) and 80.3% being retained in care. Demographic data are shown in Tables 1 and 2.

Table 1

Demographics of RWHAP Clients Receiving Outpatient Ambulatory Medical Care in the RWHAP and the Aggregate Sample

	Population $N = 304,366$		Sample $N = 428$	
			f	%
Age	*M*=44.6 *SD*=12.3		*M*=46.3 *SD*=11.9	
Race/Ethnicity				
White	75,680	25.1	93	21.9
Black	140,668	46.6	217	51.2
Asian	3,759	1.2	3	.7
Native Hawaiian/ Pacific Islander	435	.1	0	0
American Indian/ Alaska Native	1,263	.4	2	.5
Multiracial	5,594	1.9	15	3.5
Hispanic	74,328	24.6	94	22.2
Missing	2,639		4	

	Population $N = 304,366$		Sample $N = 428$	
			f	%
Gender				
Male	215,606	70.8	305	71.3
Female	85,633	28.1	122	28.5
Transgender	2,973	1.0	1	.2
Type of Health Care Coverage				
None	90,657	30.4	107	25.4
Medicare Only	26,130	8.8	44	10.5
Private Employer	18,620	6.2	16	3.8
Private Individual	16,060	5.4	11	2.6
Medicaid Only	92,875	31.1	145	34.4
VA/TriCare	451	.2	0	0
Indian Health Services	71	.0	0	0
Other	11,868	4.0	17	4.0
Medicare and Medicaid	19,165	6.4	52	12.4
More than one type	22,312	7.5	29	6.9
Missing	6,157		7	
Poverty Level				
>500%	6,908	2.4	4	1.0
401% - 500%	5,345	1.8	6	1.4
251% - 400%	15,060	5.2	17	4.1
139% - 250%	42,9695	14.8	50	12.1
101% -138%	35,410	11.6	40	9.6
<100%	184,891	63.6	299	71.9
Missing	13,787		12	
Last Viral Load Test	*M*=15,104.4 *SD*=288,971.3 Missing=21,684		*M*=14,330.9 *SD*=86,422.3 Missing=18	
Virally Suppressed				
Yes	230,195	81.4	327	79.8
No	52,487	18.6	83	20.2
Missing	21,684		18	
Last CD4 Count	*M*= 610.2 *SD*=2,974.7 Missing=17,683		*M*=545.7 *SD*=312.9 Missing=18	
CD4 Case Definition				
Stage 1	160,506	56.0	204	49.8
Stage 2	95,578	33.3	153	37.3
Stage 3	30,599	10.7	53	12.9
Missing	17,683		18	

(table continues)

	Population $N = 304,366$		Sample $N = 428$	
			f	%
Retained in Care				
Yes	217,764	80.3	323	81.8
No	53,320	19.7	72	18.2
Missing	33,282		33	

Table 2

Demographics of RWHAP Clients Receiving Outpatient Ambulatory Medical Care for Each Nutrition Assistance Category

	Receiving Food Assistance $N = 107$		Receiving MNT $N = 107$		Receiving Food Assistance and MNT $N = 107$		Receiving Food Assistance, MNT, or Food Assistance and MNT (Any Assistance) $N = 321$		Not Receiving Any Nutrition Assistance $N = 107$	
	f	%	*f*	%	*f*	%	*f*	%	*f*	%
Age	*M*=45.8 *SD*=11.2		*M*=46.1 *SD*=13.7		*M*=49.1 *SD*=10.9		*M*=47.0 *SD*=12.0		*M*=44.4 *SD*=11.5	
Race/Ethnicity										
White	26	24.5	24	22.6	17	15.9	67	21.0	26	24.8
Black	55	51.9	49	46.2	69	64.5	173	54.2	44	41.9
Asian	1	0.9	0	0	1	0.9	2	0.6	1	1.0
Native Hawaiian/ Pacific Islander	0	0	0	0	0	0	0	0	0	0
American Indian/ Alaska Native	1	0.9	0	0	0	0	1	0.3	1	1.0
Multiracial	6	5.7	7	0.9	6	5.6	13	4.1	2	1.9
Hispanic	17	16.0	32	30.2	14	13.1	63	19.7	31	29.5
Missing	1		1		0		2		2	
Gender										
Male	79	73.8	74	69.2	71	66.4	224	69.8	81	75.7
Female	27	25.2	33	30.8	36	33.6	96	29.9	26	24.3
Transgender	1	0.9	0	0	0		1	0.3	0	
Type of Health Care Coverage										
None	27	26.0	19	18.1	20	18.7	66	20.9	41	39.0
Medicare Only	9	8.7	11	10.5	15	14.0	35	11.1	9	8.6
Private Employer	4	3.8	9	8.6	0	0	13	4.1	3	2.9
Private Individual	3	2.9	4	3.8	0	0	7	2.2	4	3.8
Medicaid Only	32	30.8	42	40.0	41	38.3	115	36.4	30	28.6
VA/TriCare	0	0	0	0	0	0	0	0	0	0
Indian Health Services	0	0	0	0	0	0	0	0	0	0
Other	2	1.9	3	2.9	6	5.6	11	3.5	6	5.7
Medicare and	17	16.3	11	10.5	19	17.8	47	14.9	5	4.8

(table continues)

	Receiving Food Assistance *N* = 107		Receiving MNT *N*= 107		Receiving Food Assistance and MNT *N*= 107		Receiving Food Assistance, MNT, or Food Assistance and MNT (Any Assistance) *N*= 321		Not Receiving Any Nutrition Assistance *N* = 107	
	f	%	*f*	%	*f*	%	*f*	%	*f*	%
Medicaid										
More than one type	10	9.6	6	5.7	6	5.6	22	7.0	7	6.7
Missing	3		2		0		5		2	
Poverty Level										
>500%	1	1.0	0	0	2	1.9	3	1.0	1	1.0
401% - 500%	1	1.0	1	1.0	3	2.8	5	1.6	1	1.0
251% - 400%	5	4.9	5	4.7	2	1.9	12	3.8	5	4.8
139% - 250%	8	7.7	14	13.7	9	8.4	31	9.9	19	18.2
101% -138%	7	6.8	12	11.8	13	12.1	32	10.3	8	7.7
<100%	81	78.6	70	65.4	78	72.9	229	73.4	70	67.3
Missing	4		5		0		9		3	
Last Viral Load Test	*M*=9,483.4 *SD*=56,328.3 Missing=7		*M*=15,990.5 *SD*=80,672.5 Missing=5		*M*=23,037.8 *SD*=137,815.4 Missing=1		*M*=16,303.1 *SD*=98,443.4 Missing=13		*M*=8,375.4 *SD*=27,206.0 Missing=5	
Virally Suppressed										
Yes	75	75	89	87.3	84	79.2	248	80.5	79	77.5
No	25	25	13	12.7	22	20.8	60	19.5	23	22.5
Missing	7		5		1		13		5	
Last CD4 Count	*M*=523.8 *SD*=297.0 Missing=6		*M*=565.2 *SD*=319.2 Missing=4		*M*=522.6 *SD*=321.4 Missing=2		*M*=537.2 *SD*=312.5 Missing=12		*M*=571.6 *SD*=314.2 Missing=6	
CD4 Case Definition										
Stage 1	48	47.5	54	52.4	50	47.6	152	49.2	52	51.5
Stage 2	40	39.6	37	35.9	39	37.1	116	37.5	37	36.6
Stage 3	13	12.9	12	11.7	16	15.2	41	13.3	12	11.9
Missing	6		4		2		12		6	
Retained in Care										
Yes	73	77.7	91	88.3	88	85.4	252	84.0	71	74.7
No	21	22.3	12	11.7	15	14.6	48	16.0	24	25.3
Missing	13		4		4		12		12	

Table 3 presents the results of the tests for representativeness of the full aggregate sample to the population of clients receiving outpatient ambulatory medical services through the RWHAP in 2014. For categorical variables, the chi-square goodness of fit was used. To compare the means of the actual viral load test, actual CD4 test, and age for the full aggregate sample to the population of clients receiving outpatient ambulatory medical services, a one sample *t* test was used.

Table 3

Representative Comparison of Full Study Sample to Population of RWHAP Clients Receiving Outpatient Ambulatory Medical Care

Variable	RWHAP Population *N*=304,366	Study Sample *N*=428	One Sample *t*-test	*df*	*p*-value
Mean Last viral load test	15,104.4	14,330.9	-0.181	409	.856
Mean Last CD4 count	610.2	545.7	-4.177	409	<.001*
Mean Age	44.6	46.3	3.012	427	.003
Variable	RWHAP Population *N*=304,366	Study Sample *N*=428	Chi Square	*df*	*p*-value
Race/Ethnicity**					
White	.251	.219	56.858	5	<.001*
Black	.466	.512			
Asian	.012	.007			
Native Hawaiian/ Pacific Islander	.001	0			
American Indian /Alaska Native	.004	.005			
Multiracial	.019	.035			
Hispanic	.246	.222			
Gender**					
Male	.708	.713	2.548	2	.280
Female	.281	.285			
Transgender	.010	.002			

(table continues)

Type of Health Care Coverage					
None	.304	.254	39.654	7	<.001*
Medicare Only	.088	.105			
Private Employer	.062	.038			
Private Individual	.054	.026			
Medicaid Only	.311	.344			
VA/TriCare	.002	0			
Indian Health Services	<.001	0			
Other	.040	.040			
Medicare and Medicaid	.064	.124			
More than one type	.075	.069			
Poverty Level					
>500%	2.4	1.0	14.283	6	.027*
401% - 500%	1.8	1.4			
251% - 400%	5.2	4.1			
139% - 250%	14.8	12.1			
101% -138%	11.6	9.6			
<100%	63.6	71.9			
Virally Suppressed					
Yes	.814	.798	.732	1	.392
No	.186	.202			
CD4 Case Definition					
Stage 1	.560	.498	6.741	2	.034*
Stage 2	.333	.373			
Stage 3	.107	.129			
Retained in Care					
Yes	.803	.818	.541	1	.462
No	.197	.182			

df = degrees of freedom
*$p<0.05$
**One or more cells have expected counts less than 5

Tables 4 through 8 below presents the results of the tests for representativeness of the each of the individual sample groups of nutrition assistance to the population of

clients receiving outpatient ambulatory medical services through the RWHAP in 2014. For categorical variables, the chi square goodness of fit was used. For other variables, a one sample *t*-test was used.

Table 4

Representative Comparison of Sample of RWHAP Clients Receiving Food Assistance to Population of RWHAP Clients Receiving Outpatient Ambulatory Medical Care

Variable	RWHAP Population *N*=304,366	Study Sample *N*=107	One Sample *t*-test	*df*	*p*-value
Mean Last viral load test	15,104.4	9,483.4	-.998	99	.321
Mean Last CD4 count	610.2	523.8	-2.939	100	.004*
Mean Age	44.6	45.8	1.110	106	.269
Variable	**RWHAP Population *N*=304,366**	**Study Sample *N*=107**	**Chi Square**	***df***	***p*-value**
Race/Ethnicity**			12.513	5	.028*
White	.251	.245			
Black	.466	.519			
Asian	.012	.009			
Native Hawaiian/ Pacific Islander	.001	0			
American Indian /Alaska Native	.004	.009			
Multiracial	.019	.057			
Hispanic	.246	.160			
Gender**			2352.795	2	<.001*
Male	.708	.738			
Female	.281	.252			
Transgender	.010	.009			

(table continues)

Type of Health Care Coverage			20.604	7	.004*
None	.304	.260			
Medicare Only	.088	.087			
Private Employer	.062	.038			
Private Individual	.054	.029			
Medicaid Only	.311	.308			
VA/TriCare	.002	0			
Indian Health Services	<.001	0			
Other	.040	.019			
Medicare and Medicaid	.064	.163			
More than one type	.075	.096			
Poverty Level**			10.990	6	.089
>500%	2.4	.010			
401% - 500%	1.8	.010			
251% - 400%	5.2	.049			
139% - 250%	14.8	.077			
101% -138%	11.6	.068			
<100%	63.6	.786			
Virally Suppressed			2.512	1	.113
Yes	.814	.777			
No	.186	.223			
CD4 Case Definition			2.946	2	.229
Stage 1	.560	.475			
Stage 2	.333	.396			
Stage 3	.107	.129			
Retained in Care			.769	1	.381
Yes	.803	.777			
No	.197	.223			

df = degrees of freedom
*$p<0.05$
**One or more cells have expected counts less than 5

Table 5

Representative Comparison of Sample of RWHAP Clients Receiving MNT to Population of RWHAP Clients Receiving Outpatient Ambulatory Medical Care

Variable	RWHAP Population *N*=304,366	Study Sample *N*=107	One Sample *t*-test	*df*	*p*-value
Mean Last viral load test	15,104.4	15,990.5	.111	101	.912
Mean Last CD4 count	610.2	565.2	-1.442	102	.152
Mean Age	44.6	46.1	1.116	106	.267

Variable	RWHAP Population *N*=304,366	Study Sample *N*=107	Chi Square	*df*	*p*-value
Race/Ethnicity**			2.042	3	.564
White	.251	.226			
Black	.466	.462			
Asian	.012	0			
Native Hawaiian/ Pacific Islander	.001	0			
American Indian /Alaska Native	.004	0			
Multiracial	.019	.009			
Hispanic	.246	.302			
Gender			.318	1	.573
Male	.708	69.2			
Female	.281	30.8			
Transgender	.010	0			

(table continues)

Type of Health Care Coverage**			13.172	7	.068
None	.304	.181			
Medicare Only	.088	.105			
Private Employer	.062	.086			
Private Individual	.054	.038			
Medicaid Only	.311	.400			
VA/TriCare	.002	0			
Indian Health Services	<.001	0			
Other	.040	.029			
Medicare and Medicaid	.064	.105			
More than one type	.075	.057			
Poverty Level**			1.599	5	.901
>500%	2.4	0			
401% - 500%	1.8	.010			
251% - 400%	5.2	.047			
139% - 250%	14.8	.137			
101% -138%	11.6	.118			
<100%	63.6	.654			
Virally Suppressed			2.455	1	.117
Yes	.814	.873			
No	.186	.127			
CD4 Case Definition			.534	2	.766
Stage 1	.560	.524			
Stage 2	.333	.359			
Stage 3	.107	.117			
Retained in Care			4.219	1	.040*
Yes	.803	.883			
No	.197	.127			

df = degrees of freedom
*$p<0.05$
**One or more cells have expected counts less than 5

Table 6

Representative Comparison of Sample of RWHAP Clients Receiving Food Assistance and MNT to Population of RWHAP Clients Receiving Outpatient Ambulatory Medical Care

Variable	RWHAP Population *N*=304,366	Study Sample *N*=107	One Sample *t*-test	*df*	*p*-value
Mean Last viral load test	15,104.4	23,037.8	.593	105	.555
Mean Last CD4 count	610.2	522.6	-2.807	104	.006*
Mean Age	44.6	49.1	4.311	106	<.001*

Variable	RWHAP Population *N*=304,366	Study Sample *N*=107	Chi Square	*df*	*p*-value
Race/Ethnicity**			24.384	4	<.001*
White	.251	.159			
Black	.466	.645			
Asian	.012	.009			
Native Hawaiian/ Pacific Islander	.001	0			
American Indian /Alaska Native	.004	0			
Multiracial	.019	.056			
Hispanic	.246	.131			
Gender			1.457	1	.227
Male	.708	66.4			
Female	.281	33.6			
Transgender	.010				

(table continues)

Type of Health Care Coverage**			27.347	5	<.001*
None	.304	.187			
Medicare Only	.088	.140			
Private Employer	.062	0			
Private Individual	.054	0			
Medicaid Only	.311	.383			
VA/TriCare	.002	0			
Indian Health Services	<.001	0			
Other	.040	.056			
Medicare and Medicaid	.064	.178			
More than one type	.075	.056			
Poverty Level**			7.687	6	.262
>500%	2.4	1.9			
401% - 500%	1.8	2.8			
251% - 400%	5.2	1.9			
139% - 250%	14.8	8.4			
101% -138%	11.6	12.1			
<100%	63.6	72.9			
Virally Suppressed			.325	1	.569
Yes	.814	.792			
No	.186	.208			
CD4 Case Definition			3.804	2	.149
Stage 1	.560	.476			
Stage 2	.333	.371			
Stage	.107	.152			
Retained in Care			1.718	1	.190
Yes	.803	.854			
No	.197	.146			

df = degrees of freedom
*$p<0.05$
**One or more cells have expected counts less than 5

Table 7

Representative Comparison of Sample of RWHAP Clients Receiving Food Assistance, MNT, or Food Assistance and MNT to Population of RWHAP Clients Receiving Outpatient Ambulatory Medical Care

Variable	RWHAP Population *N*=304,366	Study Sample *N*=321	One Sample *t*-test	*df*	*p*-value
Mean Last viral load test	15,104.4	16,303.1	.214	307	.831
Mean Last CD4 count	610.2	537.2	-4.130	308	<.001*
Mean Age	44.6	47.0	3.575	320	<.001*
Variable	RWHAP Population *N*=304,366	Study Sample *N*=321	Chi Square	*df*	*p*-value
Race/Ethnicity**			18.011	5	.003*
White	.251	.210			
Black	.466	.542			
Asian	.012	.006			
Native Hawaiian/ Pacific Islander	.001	0			
American Indian /Alaska Native	.004	.003			
Multiracial	.019	.041			
Hispanic	.246	.197			
Gender**			1.823	2	.402
Male	.708	.698			
Female	.281	.299			
Transgender	.010	.003			

(table continues)

Type of Health Care Coverage			218.917	7	<.001*
None	.304	.209			
Medicare Only	.088	.111			
Private Employer	.062	.041			
Private Individual	.054	.022			
Medicaid Only	.311	.364			
VA/TriCare	.002	0			
Indian Health Services	<.001	0			
Other	.040	.035			
Medicare and Medicaid	.064	.149			
More than one type	.075	.070			
Poverty Level			15.561	6	.016*
>500%	2.4	.010			
401% - 500%	1.8	.016			
251% - 400%	5.2	.038			
139% - 250%	14.8	.099			
101% -138%	11.6	.103			
<100%	63.6	.734			
Virally Suppressed			.158	1	.691
Yes	.814	.805			
No	.186	.195			
CD4 Case Definition			6.132	2	.047
Stage 1	.560	.492			
Stage 2	.333	.375			
Stage 3	.107	.133			
Retained in Care			2.596	1	.107
Yes	.803	.805			
No	.197	.160			

df= degrees of freedom
*$p<0.05$
**One or more cells have expected counts less than 5

Table 8

Representative Comparison of Sample of RWHAP Clients Not Receiving Any Nutrition Assistance to Population of RWHAP Clients Receiving Outpatient Ambulatory Medical Care

Variable	RWHAP Population *N*=304,366	Study Sample *N*=107	One Sample *t*-test	*df*	*p*-value
Mean Last viral load test	15,104.4	8,375.4	-2.498	101	.014*
Mean Last CD4 count	610.2	571.6	-1.247	100	.215
Mean Age	44.6	44.4	-2.034	106	.044*
Variable	RWHAP Population *N*=304,366	Study Sample *N*=107	Chi Square	*df*	*p*-value
Race/Ethnicity**			2.386	5	.794
White	.251	.248			
Black	.466	.419			
Asian	.012	.010			
Native Hawaiian/ Pacific Islander	.001	0			
American Indian /Alaska Native	.004	.010			
Multiracial	.019	.019			
Hispanic	.246	.295			
Gender			.878	1	.349
Male	.708	.757			
Female	.281	.243			
Transgender	.010				

(table continues)

Type of Health Care Coverage			6.485	7	.484
None	.304	.390			
Medicare Only	.088	.086			
Private Employer	.062	.029			
Private Individual	.054	.038			
Medicaid Only	.311	.286			
VA/TriCare	.002	0			
Indian Health Services	<.001	0			
Other	.040	.057			
Medicare and Medicaid	.064	.048			
More than one type	.075	.067			
Poverty Level			4.284	6	.638
>500%	2.4	.010			
401% - 500%	1.8	.010			
251% - 400%	5.2	.048			
139% - 250%	14.8	.182			
101% -138%	11.6	.077			
<100%	63.6	.673			
Virally Suppressed			1.051	1	.305
Yes	.814	.775			
No	.186	.225			
CD4 Case Definition			.836	1	.658
Stage 1	.560	.515			
Stage 2	.333	.366			
Stage 3	.107	.119			
Retained in Care			1.859	1	.173
Yes	.803	.747			
No	.197	.253			

df= degrees of freedom
**p*<0.05
**One or more cells have expected counts less than 5

Research Question 1

Viral suppression. Results of the Pearson's chi square, presented in Table 9, found no association between receipt of any type of nutrition assistance (just food assistance, food assistance and MNT, and just MNT) and viral suppression (χ^2 = .447, p = .504). Overall, of those that had received any type of nutrition assistance (N=308), 60.5 of them were virally suppressed. Therefore, the findings failed to reject the null hypothesis in relation to the association between nutrition assistance and the HIV related health outcome of viral suppression, suggesting that receipt of nutrition assistance may not be associated with higher rates of viral suppression.

In additional analysis, also presented in Table 2, there was no association between food assistance and viral suppression (χ^2 = 1.853, *p* = .173) or receipt of MNT and food assistance (χ^2 = 023, *p* = .879) and viral suppression. There was, however, a significant association between receipt of just medical nutrition therapy (χ^2 = 4.729, *p* = .030) and viral suppression.

Table 9

Chi Square Analysis for Viral Suppression

	Virally Suppressed *N* = 410 Missing = 18				Pearson's Chi Square (χ^2)		
	Yes		No		Value	*df*	*P-Value*
	f	%	*f*	%			
Any Nutrition Assistance					.447	1	.504
Yes	248	60.5	60	14.6			
No	79	19.3	23	5.6			

(table continues)

Food Assistance					1.853	1	.173
Yes	75	18.3	25	6.1			
No	252	61.5	58	14.1			
Medical Nutrition Therapy					4.729	1	.030*
Yes	89	21.7	13	3.2			
No	238	58.0	70	17.1			
Both					.023	1	.879
Yes	84	20.5	22	5.4			
No	243	59.3	61	14.9			

*$p<0.05$
df = degrees of freedom

CD4 counts. Table 10 presents the results of the Pearson's chi square analysis for nutrition assistance and CD4 counts, using the CDC case definition. For this analysis, I recoded the value of CD4 into the CDC case definitions. CD4 counts of 500 or greater were coded as 1 for Stage 1, counts between 200 and 499 were coded as 2, for Stage 2, and those counts below 200 were coded as 3, for Stage 3.

For those patients receiving any nutrition assistance ($N = 309$), 37.1% had a CD4 count in the range of CDC case definition Stage 1, while 28.3% fell into Stage 2, and 10.0% had CD4 counts meeting the definition of Stage 3. In analyzing nutrition assistance generally, the receipt of any nutrition assistance was not associated with a higher CD4 count ($\chi^2 = 211$, $p = .900$). Therefore, these findings suggest that the null hypothesis cannot be rejected in relation to CD4 count and nutrition assistance. There was no significant association between CDC case definition stage and the receipt of just food assistance ($\chi^2 = .322$, $p = .851$), for the receipt of just medical nutrition therapy and

stage (χ^2 = .442, p = .802), or for receipt of MNT and food assistance together and stage (χ^2 = .714, p = .700).

Table 10

Chi Square Analysis for CDC Case Definition (Based on CD4 count)

	CDC Stage N = 410 Missing = 18						Pearson's Chi Square (χ^2)		
	1		2		3		Value	*df*	*P-Value*
	f	%	*f*	%	*f*	%			
Any Nutrition Assistance							.211	2	.900
Yes	152	37.4	116	28.3	41	10.0			
No	52	12.7	37	9.0	12	2.9			
Food Assistance							.097	2	.953
Yes	48	11.7	40	9.8	13	3.2			
No	156	38.0	113	27.6	40	9.8			
Medical Nutrition Therapy							.442	2	.802
Yes	54	13.2	37	9.0	12	2.9			
No	150	36.6	116	28.3	41	10.0			
Both							.714	2	.700
Yes	50	12.2	39	9.5	16	3.9			
No	154	37.6	114	27.8	37	9.0			

*p<0.05
df= degrees of freedom

Research Question 2

Of the 300 clients who received any nutrition service, 252 (63.8%) were retained in care. The retention measure was calculated as part of the data request and was provided to me as a separate variable. In Table 11, the Pearson's chi-square analysis for all types of food assistance and its association with retention in care has been presented, using HRSA's HIV/AIDS Bureau's definition of retained in care. For clients receiving

any nutrition assistance, the analysis found a significant association between the receipt of nutrition assistance services and retention in care ($\chi^2 = 4.154$, $p = .042$). This suggests that the null hypothesis for this question can be rejected.

Further analysis concluded there was a significant association between retention in care and receipt of MNT ($\chi^2 = 4.044$, $p = .044$); however, there was no significant association between food assistance and MNT ($\chi^2 = 1.255$, $p = .263$), or just nutrition assistance on its own ($\chi^2 = 1.400$, $p = .237$).

Table 11

Chi Square Analysis for Retention in Care

	Retained in Care $N = 395$ Missing = 33				Pearson's Chi Square (χ^2)		
	Yes		No		Value	*df*	*P-Value*
	f	%	*f*	%			
Any Nutrition Assistance					4.154	1	.042*
Yes	252	63.8	48	12.2			
No	71	18.0	24	6.1			
Food Assistance					1.400	1	.237
Yes	73	18.5	21	5.3			
No	250	63.3	51	12.9			
Medical Nutrition Therapy					4.044	1	.044*
Yes	91	23.0	12	3.0			
No	232	58.7	60	15.2			
Both					1.255	1	.263
Yes	88	22.3	15	3.8			
No	235	59.5	57	14.4			

*$p<0.05$
df = degrees of freedom

Additional Discussion and Analysis on Retention in Care

Additional analysis was conducted to better understand the role of retention in care in this sample for select characteristics, including race/ethnicity and health care coverage. For this section of the analysis, the sample was filtered to look only at clients receiving any nutrition assistance from the RWHAP (i.e., clients receiving food assistance, clients receiving MNT, and clients receiving both food assistance and MNT). As discussed above, of the 300 clients who received any nutrition service, 252 (63.8%) were retained in care. Table 12 presents additional analysis on factors that could impact retention in care for clients receiving any nutrition assistance. These factors include race/ethnicity, health care coverage, viral suppression, and CDC case definition. For clients receiving any nutrition assistance, the analysis found a significant association between the retention in care and viral suppression ($\chi^2 = 18.241$, $p < .001$). In addition, for the clients receiving any nutrition assistance, there is not a significant association between retention in care and race/ethnicity ($\chi^2 = 4.062$, $p = .541$), insurance status and retention in care ($\chi^2 = 7.708$, $p = .359$) or retention in care and CDC case definition for CD4 counts ($\chi^2 = 1.137$, $p = .566$).

Table 12

Additional Chi Square Analysis for Retention in Care in RWHAP Clients Receiving Any Nutrition Assistance

	Retained in Care $N = 300$ Missing = 21				Pearson's Chi Square (χ^2)		
	Yes		No		Value	*df*	*P-Value*
	f	%	*f*	%			
Race/Ethnicity**					4.062	5	.541
White	48	16.1	13	4.4			
Black	141	47.3	25	8.4			

(table continues)

Asian	1	0.3	1	0.3				
American Indian/Alaska Native	1	0.3	0	0				
Multiracial	8	2.7	2	0.7				
Hispanic	51	17.1	7	2.3				
Missing					2			
Health care Coverage**						7.708	7	.359
No Insurance	48	16.3	14	4.7				
Medicare	29	9.8	4	1.4				
Private Employer	10	3.4	2	0.7				
Private Individual	7	2.4	0	0				
Medicaid	91	30.8	16	5.4				
Other	11	3.7	0	0				
Medicare and Medicaid	41	13.9	4	1.4				
Multiple Insurance	15	5.1	3	1.0				
Missing					5			
Viral Suppression						18.241	1	<.001*
Yes	211	72.8	24	8.3				
No	37	12.8	18	6.2				
Missing					10			
CDC Case Definition						1.137	2	.566
Stage 1	125	43.3	17	5.9				
Stage 2	91	31.5	18	6.2				
Stage 3	32	11.1	6	2.1				
Missing								

*p<0.05
**One or more cells have expected counts less than 5
df = degrees of freedom

Logistic Regression

Addition analysis was done for any significant results to determine the impact of selected demographic variables on these health outcomes. In previous analysis, significant results were found for viral suppression and MNT, as well as for retention in care and the recipient of any nutrition service and for retention in care and MNT. Separate models were run for each of these relationships and included the covariates of age, race/ethnicity, and gender.

Viral suppression. Logistic regression was run to determine the impact of MNT, gender, age, and race/ethnicity on viral suppression and the results are presented in Table 13. Odds ratios were calculated and presented below. A test of the full model against all of the independent variables was significant, χ^2 ($df = 4$) = 21.962, $p \leq 0.001$. The model explained 8.3% of the variance in viral suppression (Nagelkerke R^2). The Wald criterion indicate that MNT ($p = 0.03$) and age ($p = 0.001$) were significant predictors of viral suppression. Gender and race/ethnicity were not significant predictors.

Table 13

Logistic Regression Results for Viral Suppression

Predictors	β	Exp (β)	*95% CI*
MNT	717	2.047*	1.062, 3.946
Gender	-.401	.669	.395, 1.135
Age	.038	1.039*	1.016, 1.062
Race/Ethnicity	.097	1.102	.997, 1.218

* = $p \leq 0.05$

Retention in care. Logistic regression was run to determine the impact of receipt of any nutrition service (food assistance, MNT, or both), gender, age, and race/ethnicity on retention in care and the results are presented in Table 14. A test of the full model against all of the independent variables was significant, χ^2 ($df = 4$) = 7.692, $p = 0.104$. The model explained 3.2% of the variance in viral suppression (Nagelkerke R^2). The Wald criterion indicate that none of the predictors included in the model were significant predictors of retention in care.

Logistic regression was also run to determine the effect of MNT, gender, age, and race/ethnicity on retention in care. These results are also presented in Table 14 below,

including the odds ratio. A test of the full model against all of the independent variables was not significant, χ^2 ($df = 4$) = 8.662, $p \leq 0.070$. The model explained 3.6% of the variance in viral suppression (Nagelkerke R^2). The Wald criterion indicate that none of the factors included in model were significant predictors of retention in care.

Table 14

Logistic Regression Results for Retention in Care

	Predictors	β	Exp (β)	*95% CI*
Retention in Care and Any Nutrition				
	Any Nutrition	.506	1.658	.935, 2.940
	Gender	.131	1.140	.638, 2.036
	Age	.017	1.017	.995, 1.040
	Race/Ethnicity	.071	1.074	.969, 1.189
Retention in Care and MNT				
	MNT	.643	1.902	.971, 3.725
	Gender	.151	1.163	.652, 2.073
	Age	.020	1.020	.998, 1.043
	Race/Ethnicity	.060	1.062	.958, 1.177

*= $p \leq 0.05$

Summary

The results of this study show relevant results related to receipt of nutrition assistance and HIV-related health outcomes. The study sought to answer questions as to whether the receipt of food assistance or MNT was associated with the specific HIV-related health outcome of viral suppression, CD4 count, and retention in care. Pearson's chi square test was used to determine if there were associations between food assistance and viral suppression, CD4 count, and retention in care or associations between MNT and these outcome variables of interest.

Results suggest that there is no association between viral suppression and receipt of nutrition services, or between a client's CD4 count (based on CDC case definition stage) and receipt of nutrition services. There does appear to be a statistically significant association between receipt of MNT and viral suppression. For viral suppression and the other nutrition services, there is not an association for receipt of food assistance or both food assistance and MNT together. For CD4 count, there also does not appear to be a significant association for receipt of food assistance, MNT, or both. Regarding retention in care, there also is a significant association between receipt of any nutrition assistance and retention in care. When broken down, there is also a significant association between MNT and retention in care; however, there is not one between retention and food assistance or receipt of both MNT and food assistance. Additional analysis and comparison was also presented on retention in care. In additional logistic regression was presented to examine the impact of demographic variables of age, gender, and race/ethnicity on viral suppression and retention in care.

Chapter 5 will provide a more detailed discussion of these results and provide an interpretation of the findings. In addition, it will discuss the implications of these findings for social change and what the next steps for research on this topic could be.

Chapter 5: Discussion, Conclusions, and Recommendations

Using RSR data, I examined the association between the receipt of RWHAP services of food assistance and medical nutrition therapy and the HIV-related health outcomes of viral suppression, CD4 counts, and retention in care. In Chapter 5, I summarize and interpret the key findings of this study. I then discuss the study's limitations, provide recommendations for addressing gaps in research uncovered by this study, and discuss the implications this study may have for practice and for social change. The results of this study indicated that MNT may have been associated with being retained in care, as well as being virally suppressed, while the receipt of any nutrition service (food assistance, MNT, or both) was associated with retention in care.

Interpretation of Findings

I tested two hypotheses related to the receipt of nutrition assistance and HIV-related health outcomes. To test these hypotheses, I gathered a systematic sample of 428 RWHAP clients from the 2014 RSR. Clients were 13 years or older and had received at least one outpatient ambulatory medical visit in the reporting year. Equal representation was taken from clients who received food assistance, MNT, both food assistance and MNT, and no nutrition assistance. I hypothesized that there would be an association between receipt of nutrition assistance (any type, food assistance, MNT, both food assistance and MNT) and viral suppression, level of CD4, and retention in care.

I conducted one sample *t* tests and chi-square goodness of fit tests on each of the sample groups (food assistance, MNT, food assistance and MNT, no nutrition assistance, and any nutrition assistance) to determine whether the sample was similar to the

population from which it was taken. I conducted analysis for last viral load test, last CD4 count, age, race/ethnicity, gender, type of health care coverage, poverty level, viral suppression, CDC case definition, and retention in care. For the food assistance sample, the one sample *t* tests yielded significant results for the last CD4 count, while the chi-square goodness of fit tests resulted in significant results for race/ethnicity, gender, and type of health care coverage. For the MNT sample, the one sample *t* tests yielded no significant results, while the chi-square goodness of fit tests had significant results for retention in care. For the food assistance and MNT sample, the one sample *t* tests yielded significant results for last CD4 count and age, while the chi-square goodness of fit tests had significant results for race/ethnicity and type of health care coverage. For the any nutrition assistance sample, the one sample *t* tests yielded significant results for last CD4 count and age, while the chi-square goodness of fit tests had significant results for race/ethnicity, type of health care coverage, poverty level, and CDC case definition. For the no nutrition assistance sample, the one sample *t* tests yielded significant results for last viral load test and age, while the chi-square goodness of fit tests had no significant results. These significant results suggest that the sample was not representative of the full RWHAP population age 13 or older who received an outpatient ambulatory medical visit in the reporting year, and sampling bias may have occurred. The results appear to show poor external validity on the analysis of these variables. For the nonsignificant results, the population and the sample were similar for these attributes.

Research Question 1

Viral suppression. I found that, after testing the null hypothesis, 83% (89 of 107) of clients receiving MNT were virally suppressed, a significant association ($p \leq 0.05$). This is consistent with current literature, where those receiving nutrition education, a component of MNT, were less likely to be food insecure (Oketch et al., 2011). Being food insecure places the individual at greater risk for not being virally suppressed (Wang et al., 2011). Although much of the published research for food assistance was conducted in resource poor areas, findings from this study are less consistent with published literature, which has shown that food assistance can improve viral suppression (Franke et al., 2013) and improve other HIV-related health outcomes (Maluccio et al., 2015; Rawat et al., 2010). This finding also supports Andersen's behavioral health model for vulnerable populations, which suggests that receipt of information and services (such as MNT) can have an impact on the health outcomes of a vulnerable person (in this case a PLWH).

CDC case definition (based on CD4 count). I found no statistically significant difference in CDC case definition and receipt of nutrition assistance in any form. Although there was limited research related to CD4 count and any form of nutrition assistance to support any results, using the framework of Andersen's behavioral health model for vulnerable populations, it could be supposed that receipt of MNT or food assistance (as proxies for enabling factors of education and social support) might lead to a better CD4 count (or a lower CDC case definition). The initial analysis was conducted using a sample drawn from the population of all RWHAP clients age 13 or older who

were not missing the retention in care variable. This was done as a proxy for outpatient ambulatory medical care . This initial analysis indicated a significant association between CDC case definition and receipt of any nutrition assistance. It also indicated a significant association between case definition and receipt of food assistance. These significant associations likely occurred because the filtering on retention in care did not include anyone who only had an outpatient ambulatory medical visit after September 1 of the reporting year, artificially increasing the rate of retention in care in the sample and population, as well as other related health outcomes associated with being retained in care.

Research Question 2

Findings revealed that of the 300 clients receiving any nutrition assistance, 84.0% (252) were retained in care; 88% (73 of 103) of clients receiving MNT were retained in care. Both represent statistically significant associations (Any: $\chi^2 = 4.154$; $p = .042$, MNT: $\chi^2 = 4.044$, $p = .044$). These results support previous findings in the literature, primarily from resource poor areas that food assistance and MNT can impact retention in care. Studies in Honduras indicated that MNT improved retention and led to few missed visits (Martinez et al., 2014). A study in Rwanda indicated that food assistance can help patients improve their retention (Franke et al., 2013). There was limited research that addressed MNT and food assistance together, but according to Andersen's behavioral health model for vulnerable populations, food assistance and MNT together may lead to improvements in retention in care.

The initial analysis, in which I filtered incorrectly on retention in care, indicated significant associations between retention in care and receipt of food assistance, receipt of MNT, and receipt of both food assistance and MNT. These significant associations likely resulted because the filtering on retention in care did not include anyone who only had an outpatient ambulatory medical visit after September 1 of the reporting year, artificially increasing the rate of retention in care in the sample.

Limitations

The primary limitation of this study was the data. The RSR is primarily intended for program evaluation, and the data set is not designed or collected for research purposes. This means that certain aspects of the data make it more difficult to draw strong conclusions, and the results of this study may not be generalizable beyond the RWHAP population.

Another limitation of this study was that there were nearly 190,000 PLWH served by the RWHAP who were excluded from the analysis because they had not received medical care through the program. As a result, no clinical data were collected and retention in care could not be calculated. Although this was consistent with data usage and analyses conducted by the HIV/AIDS Bureau, it must be mentioned as a limitation because excluding these clients may have in some way biased the results.

In addition, receipt of food assistance and MNT were reported as yes or no. There was no date attached to the receipt of service or indication of the number of times the service was received, so the receipt of either or both of these services cannot be clearly linked to a specific CD4 count or a viral load test. This means that the viral load test

could have been taken prior to, with, and/or after the service was provided. If a client received both food assistance and MNT in the reported year, the timing of both of these services in relation to one another also could not be determined. Because direct relationships could not be determined, Pearson's chi-square test was used for the analysis of the data.

In addition, the RSR puts all food assistance services into one category. This includes food received at a food pantry, a hot meal provided at a meal site, a home delivered meal, nutritional supplements not provided under the care of a medical professional, and vouchers given to purchase food. There was a similar challenge for MNT because it was only known that MNT was provided. This meant that individual items could not be separated to determine whether one category or type of service was more significant than another.

Recommendations

Given the limitations of this study, additional research is recommended in this area, especially prospective research using primary data. It is recommended that a study be conducted using a cross-section of RWHAP sites that provide nutrition assistance, preferably with standardized intervention protocols across sites so that outcomes can be assessed and attributed to the interventions. Being able to establish direct relationships between the role of each type of nutrition assistance and HIV-related health outcomes of viral suppression, CD4 count, and retention in care can provide additional insight into how to best support PLWH throughout the HIV care continuum, both in the RWHAP and

in the general population. This is especially important in being able to link the service to the health outcome, which could not be done through the data used for this study.

In addition, it would be useful to have more detailed knowledge of what nutrition assistance looks like in the RWHAP. Additional information is recommended to understand what services are being provided under the categories of food assistance and MNT that are being reported to the RSR. Food assistance can include supplements that are not provided under the order of a registered dietitian, foods that are taken home and prepared, hot meals eaten at a meal site, home delivered meals, vouchers for food, and water filtration systems. Each of these may have a different impact on health outcomes that could not be assessed in this study. MNT can include not only nutrition assessment, dietary evaluation, and nutrition counseling, but also provision of supplements and food under the supervision of a registered dietitian.

In addition, it may be important to examine the role of nutrition quality in the foods being provided. This study did not address whether the foods provided were of high nutritional quality and met the nutritional needs of the clients receiving services through the program. The quality of the food provided may have impacted the health of the clients.

Implications

Nutrition is important in HIV care and in public health generally. This study lays the foundation for better understanding of the role of nutrition assistance in the RWHAP and in HIV care. Understanding how nutrition assistance, in all its forms, support PLWH is important and may lead to programmatic improvements and policy changes. Nutrition

services have not been well studied in the RWHAP, so identifying associations between these services and positive HIV-related health outcomes may lead to program improvements. Program improvements and policy changes may lead to better health outcomes for people receiving these services through the RWHAP. I found an association between receipt of any nutrition service and retention in care, as well as between MNT and viral suppression and MNT and retention in care. This suggests a role for these services within the program and the potential need for these services to be examined more closely, both at the national level and within the individual recipients/grantees who are providing HIV-related services to PLWH.

Conclusions

The findings of this study indicated associations between receipt of certain nutrition assistance services in the RWHAP and HIV-related health outcomes. Although additional research is needed to better understand the role of food assistance and MNT in the RWHAP, this study lays the groundwork for that additional study. This study showed that certain nutrition services, MNT in particular, are important to the HIV-related health outcomes of the PLWH served by the RWHAP and can help inform the program's direction and policy for nutrition services. This may include guidance or best practices regarding nutrition services or additional funding to study the nutrition services provided through the RWHAP. This, in turn, may lead to improved health outcomes within the RWHAP.

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Appendix A: Data Use Agreement

DATA USE AGREEMENT

This Data Use Agreement ("Agreement") is entered into on July 22, 2016, by and between the Health Resources and Services Administration ("HRSA"), U.S. Department of Health and Human Services ("HHS"), having an address at 5600 Fishers Lane, Rockville, MD 20857 and Theresa Jumento having an address at 246 Bishops Glen Dr., Frederick, MD 21702 collectively "the Parties."

WHEREAS, the HRSA HIV/AIDS Bureau (HAB) will assist Theresa Jumento in providing data for the purposes of completing her doctor of philosophy (Ph.D.) in public health at Walden University, College of Health Sciences located in Minneapolis, Minnesota. The research will look at the role of nutrition services (medical nutrition therapy and food banking) on health outcomes of CD4, retention in care, and viral suppression in Ryan White HIV/AIDS Program clients receiving those services, as compared to those that do not receive nutrition services. This data will be used in a secondary analysis of client level data.

WHEREAS, HAB has provided Ryan White Services Report Data including client level demographic data, clinical information, and receipt of service information, to Theresa Jumento, where "Ryan White Services Report Data" means HRSA's cleaned, processed, de-duplicated records for Ryan White Services Report data submitted by HAB grantees and service providers. The Ryan White Services Report data does not include personally identifiable information.

THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. Ownership – The Parties mutually agree that HRSA retains all ownership rights to the Ryan White Services Report data referred to in this Agreement and that Theresa Jumento does not obtain any right, title, or interest in the Ryan White Services Report data provided by HAB. c

2. Permissible use – Theresa Jumento shall use the Ryan White Services Report data solely for the purposes of carrying out the tasks previously described above. Theresa Jumento shall not use the Ryan White Services Report data for any other purpose without prior written permission from HRSA.

3. Security of data – Theresa Jumento shall appropriately secure the Ryan White Services Report data using safeguards providing at least the level and scope of security established by the Office of Management and Budget (OMB) in OMB Circular No. A-130, Appendix III – Security of Federal Automated Information Systems. Theresa Jumento shall also comply with applicable HHS policies on information security, including HHS-OCIO Policy for Information Systems Security and Privacy and other policies referenced therein. For purposes of this Agreement, appropriate security measures include but are not limited to:

   - Limited access to data only by study staff specified in the request for proposal;
   - Encryption of data or password protection when data is not in use; and

- Storage of data in secured settings. Note that data may not be stored on a laptop computer or external drive unless the data is appropriately encrypted.[1]

4. Dissemination of data –
   a. Theresa Jumento shall not publish, release, disseminate, or grant others access to the Ryan White Services Report data except as expressly permitted by written authorization from HRSA.
   b. Theresa Jumento shall submit to HAB any drafts (including but not limited to analyses, summaries, reports, and articles) resulting from the use of HRSA's Ryan White Services Report data prior to publication or release, and HAB shall provide a written response to Theresa Jumento within 30 days of HAB's receipt of the submission. Theresa Jumento will not publish or otherwise release the draft prior to the 30 day period. The written response will not prohibit publication or release of the draft but may include, for example, a request to include a disclaimer.

5. Destruction of data – After Theresa Jumento has completed all tasks as previously described, Theresa Jumento shall destroy the Ryan White Services Report data provided by HAB in connection with the tasks previously described, using appropriate destruction methods recommended by the National Institute of Standards and Technology in Guidelines for Media Sanitization (NIST Special Publication 800-88) and any updates thereto.

6. Acknowledgment – In all reports based on the Ryan White Services Report data, Theresa Jumento shall acknowledge HRSA as the original source of the data.

The undersigned warrants that he or she is authorized to enter into this Agreement on behalf of Theresa Jumento and agrees to all the terms specified herein.

Theresa Jumento — 7/22/16

Theresa Jumento, Student/Researcher — DATE

7/25/16

Antigone Dempsey — DATE
Division of Policy and Data
HIV/AIDS Bureau
Health Resources and Services Administration
U.S. Department of Health and Human Services

[1] http://www.hhs.gov/ocio/policy/hhs-ocio-2011-0003.html, Section 5.32 Federal Employees and Contractors : *5.32.8 "Ensuring that sensitive information is not stored on laptop computers or other portable devices unless the data is secured using encryption standards commensurate with the sensitivity level of the data;"*

Appendix B: Variable Coding

Variable	Value	Label*
Age	Actual Age in Years	Age in Years
Gender	.	Missing/Unknown
	1	Male
	2	Female
	3	Transgender
Housing Status	1	Stable
	2	Temporarily Housed
	3	Unstably Housed
Outpatient Ambulatory Medical Care (OAMC)	0	No OAMC Visit During the Reporting Year
	1	At least one OAMC Visit During the Reporting Year
OAMC Visits	Actual Number of Visits	Actual Number of OAMC Visits in the Reporting Year
Insurance Status	0	No Insurance
	2	Medicare Only
	10	Private Insurance
	11	Private Employer
	12	Medicaid Only
	13	VA/TriCare
	14	Indian Health Service
	15	Other
	22	Dual Medicaid and Medicare
	100	Multiple
Poverty Level	7	>500% of Federal Poverty Level (FPL)
	8	401% - 500%
	9	101% - 138%
	10 or 11	139% - 250%**
	12	251% - 400%
	13	<100%
Race/Ethnicity	1	White
	2	Black
	3	Asian
	4	Native Hawaiian/Pacific Islander
	5	Native American/Alaskan Native

Variable	Value	Label*
	7	Multi-racial
	8	Hispanic
Risk	1	Men Who Have Sex with Men (MSM)
	2	Intravenous Drug User (IDU)
	2.5	MSM IDU
	3	Coagulation Disorder
	4	Heterosexual Contact
	5	Blood Product
	6	Perinatal
	7	Other
Last Viral Load		Last actual viral load test
Last Viral Suppression	.	Missing/Unknown
	0	Not Suppressed
	1	Suppressed
Retained in Care	.	Missing/Unknown
	0	Not Retained
	1	Retained
CD4		Actual last CD4 test result
CD4 (calculated variable)	1	= or > 500
	2	200 - 499
	3	199 or lower
Nutrition Service (calculated variable)	1	Food Assistance, no MNT
	2	MNT, no Food Assistance
	3	Both Food Assistance and MNT
	4	Neither Food Assistance or MNT

*Unless noted, all labels are as define in the 2014 RSR Manual.

** There are two variables for this income range because the range was combined from two separate categories (139% - 199, and 200% - 299%)